CASE WESTERN RESERVE UNIVERSITY EST. 1826

Faculty Senate Meeting
Tuesday, November 17, 2009
3:30-5:30 p.m. – Adelbert Hall, Toepfer Room

AGENDA

3:30pm	Approval of Minutes from the September 24, 2009 Faculty Senate meeting, *attachment*	C. Musil
3:35pm	President's Announcements	B. Snyder
3:40pm	Provost's Announcements	B. Baeslack
3:45pm	Chair's Announcements	C. Musil
3:45pm	Report from the Executive Committee	A. Levine
4:10pm	CTORSP	A. Levine S. Gerson
4:20pm	Update on funding of RFP's for Strategic Alliances	R. Miller
4:35pm	Approval of new FSCUE Standing Subcommittee	G. Chottiner
4:45pm	Proposed Participation in Pilot Accreditation Process	D. Feke
4:50pm	Branding Guidelines	G. Bieler
5:05pm	Report on Undergraduate Enrollment and Retention	J. Wolcowitz
5:25pm	Faculty Senate Budget Priorities	C. Musil

CASE WESTERN RESERVE UNIVERSITY
Faculty Senate
Minutes of the Meeting of November 17, 2009
Toepfer Room, Adelbert Hall

Members present

Kathryn Adams
Keith Armitage
Bruce Averbook
Bud Baeslack
Timothy Beal
Cynthia Beall
Jessica Berg
Daniela Calvetti
Gary Chottiner
Mary Davis
Mark DeGuire
Faye Gary
Julia Grant
Sue Hinze
David Hutter
Elizabeth Kaufman
Cheryl Killion
Kenneth Ledford
Alan Levine
Frank Merat
Carol Musil
John Orlock
Daniel Ornt
Joseph Prahl
Jonathan Sadowsky
Benjamin Schechter
Barbara Snyder
Glenn Starkman
Susan Tullai-McGuinness
Michele Walsh
Shengbo Wang
David Wilson
Liz Woyczynski
Nicholas Ziats

Members Absent

Nabil Bissada
Robert Bonomo
Christine Cano
Susan Case
Martha Cathcart
Mark Chance
Angela Graves
Peter Haas
Christine Hudak
Jim Kazura
Ken Loparo
Leonard Lynn
Kalle Lyytinen
Kathryn Mercer
Shirley Moore
Diana Morris
G. Regina Nixon
Rodney Pratt
Faisal Quereshy
Roy Ritzmann
Cassandra Robertson
Samantha Schartman
Scott Shane
Mark Smith
Sorin Teich
Betsy Tracy
Georgia Wiesner
Gary Wnek
Terry Wolpaw

Others Present

Dan Anker
Chris Ash
Russell Berusch
Glenn Bieler
Rick Bischoff
Don Feke
Lara Kalafatis
Ginny Leitch
Marilyn Mobley
Glenn Nicholls
Kathy O'Linn
Timothy Robson
Chris Sheridan
Lynn Singer
Jeff Wolcowitz

Call to Order
Professor Carol Musil, chair, Faculty Senate, called the meeting to order at 3:30 p.m.

Approval of minutes
Upon motion, duly seconded, the minutes of the Faculty Senate meeting of October 26, 2009 were approved as submitted.

President's announcements
President Barbara Snyder had no announcements. She was asked about the prospects of a reinstated University Ball. It is still under consideration. To date, she received only 14 emails in response to a solicitation for feedback to the Faculty Senate. The small number of responses was disappointing. Responses were mixed; some were strongly in favor, others were equally against reinstating the University Ball.

Provost's announcements
Provost Bud Baeslack commented that 23 research proposals from the strategic planning alliances have been received. There will likely be an announcement in January, at the start of spring semester, about which proposals will be funded. The first few meetings of the Budget System Review Committee were used to educate committee members on the intricacies of the budget system; the committee will meet with the deans and a website to chart the committee's progress will be posted shortly.

Chair's announcements
Prof. Carol Musil, chair, Faculty Senate announced that the Executive Committee would hear the mid-year reports of the standing committee chairs in December and January. The interim report by the *ad hoc* SAGES Review Committee will be presented at the December meeting of the Faculty Senate. She encouraged faculty to participate in the university's Charity Choice Campaign. Members of the Senate rated the top university budget priorities as follows: 1) seed fund for best practices in undergraduate advising, 2) updated website for Faculty Senate, By-laws and Faculty Handbook, 3) fund to study the feasibility for providing elder-care benefits to faculty and staff 4) an Espresso Book Machine®, a print-on-demand device that produces library quality paperbacks at low cost 5) a stimulus project to aid undergraduate programs to build an effective outcome assessment processes. A senator expressed disappointment that proposals in support of graduate education were not top priorities. The ratings survey focused on short-term, low cost expenditures; the funding needed for graduate student scholarships is great. President Snyder said she often talks to potential donors about the university's need to provide better financial aid to all students, including graduate students. The undergraduate student representative to the Faculty Senate voiced support for endeavors to support undergraduate academic advising; the need for better academic advising is a topic of discussion in the Undergraduate Student Government (USG).

Chair-elect's announcements
Prof. Alan Levine, chair-elect, Faculty Senate summarized the November meeting of the Executive Committee. The Clinical Translational Oncology Research Scholars Program (CTORSP) was approved. The Faculty Senate Committee on Undergraduate Education (FSCUE) proposed its new standing subcommittees; a careful review of Robert's Rules determined that the Constitution presides if there is conflict with Faculty Senate By-laws. The proposed FSCUE Subcommittees will be presented for discussion at the Senate meeting, but a vote of approval is not required. The Executive Committee endorsed the proposal from the Higher Learning Commission of the North Central Association of Schools and Colleges to participate in the pilot program accreditation process. In December, the Executive

Committee will vote on the formation of an *ad hoc* committee to consider changes to the Faculty Handbook that would raise the importance of faculty-centric academic advising. And the Executive Committee approved the awarding of an honorary degree for Katie Couric, newscaster, who has acted as an advocate for colon cancer awareness, screening and research.

CTORSP

Prof. Alan Levine, chair-elect and former chair of the Faculty Senate Graduate Studies Committee, presented the Clinical Translational Oncology Research Scholars Program (CTORSP); Prof. Stan Gerson, from the Cancer Center at the School of Medicine, was present to answer questions. CTORSP is a 16-20 credit, two-year certificate program for clinical oncology junior faculty who are interested in pursuing academic research careers as physician scientists. The proposed certificate has been reviewed several times, starting in Spring 2009, by the Graduate Studies Committee and the Executive Committee. The Graduate Studies Committee examined the program to determine 1) target audience 2) academic rigor and 3) availability of faculty and funds. After more information was provided about program governance, conversion to a master degree, and student evaluations, the CTORSP was approved by the Graduate Studies Committee. It is a certificate program because there is no value added for a master degree for junior faculty already holding an MD. It does not duplicate the CRSP, which provides broad clinical science training, because the CTORSP is focused specifically on oncology. A curriculum oversight committee has been established, including Dr. Gerson. Many of the classes in the CTORSP are also part of the CRSP and those classes are reviewed and approved by the School of Medicine Faculty Council; therefore many of the classes in the CTORSP program are transferable to a master degree. There were questions about providing students with cultural competencies and disseminating research finding to the wider community; these issues are covered in the certificate program's seminar series. The listing for the proper ethics class will be corrected. Upon motion, duly seconded, the Faculty Senate voted to approve the certificate for Clinical Translational Oncology Research Scholars Program.

Update on funding of RFP's for Strategic Alliances

Prof. Robert Miller, vice dean for research, at the School of Medicine summarized the progress to date on the RFP's for the Strategic Alliances. There are 11 alliances formed as flexible, dynamic centers; they are not silos or administrative centers. All proposals need the endorsement of one of the alliances and one of the constituent faculties. Each proposal must have 1:1 matched funding from one of the schools/college and/or another school/external partner. There are 24 proposals under consideration. Total funding is about 7.5M over two years for all proposals. Each proposal can apply for up to 1 million dollars worth of funding, or 500K for each of two years. But many proposals requested less money than that. A senator offered that the alliances have been successful in creating new interdisciplinary research efforts, and that communications between schools seems to be increasing. More interdisciplinary efforts are needed for graduate programs of study.

Approval of new FSCUE Standing Subcommittees

Prof. Chottiner, chair, Faculty Senate Committee on Undergraduate Education (FSCUE), summarized the three new standing FSCUE subcommittees: the Academic Standing Subcommittee (and the Academic Standing Board), the Curriculum Subcommittee, and the Student Life Subcommittee. Prof. Chottiner detailed the membership and charge for each committee. A couple senators spoke to the importance of having faculty, not administrators, as chairs of the FSCUE subcommittees. Prof. Chottiner offered that these assignments can be changed, the UUF Committees when chaired by faculty had often been ineffective, and that the FSCUE, chaired by a faculty member, will consider and approve all policy changes presented by the FSCUE subcommittees.

Proposed Participation in Pilot Accreditation Process

Don Feke, vice provost for undergraduate education, reported that the Higher Learning Commission of the North Central Association of Schools and Colleges has offered the university an opportunity to be part of a pilot accreditation program. The pilot program will make the accreditation process easier and more productive. Case Western Reserve is 1 of 14 universities that have been asked to participate; it is the only private, research university. Any college or university that makes a good faith effort during the pilot program will get a pass at its accreditation review, regardless of the results of its quality improvement project. The university needs to improve on outcome assessment endeavors. The pilot allows the university to focus on a topic of central importance; the university's recent internationalization efforts are a possible choice. The pilot program will be discussed with the deans, and it will also be added to the agenda of the November Faculty Senate meeting. The pilot program will discussed with the deans. The Faculty Senate endorsed the university's participation in the pilot accreditation program.

Branding Guidelines

Glenn Bieler, associate vice president for marketing and communications, summarized the university's updated branding guidelines. The logo design has remains the same, but the visibility has been enhanced: the logo color is stronger and the school names are larger. A new "stacked" version is available for narrower layouts to enhance the logo's visibility. Select centers and institutes have their own logos; eligibility is determined by the president and the provost. In January the complete array of templates for presentations, etc. will be available on the web. A senator noted that the previous logo which promoted CASE in capital letters is in use. Mr. Bieler said that his office uses the full name, Case Western Reserve University, or CWRU and encourages the media to do the same. The new version of the logo with the tagline "think beyond the possible" is optional.

Report on Undergraduate Enrollment and Retention

Jeff Wolcowitz, dean of undergraduate studies, gave a report on the university's recent undergraduate enrollment and retention rates. Retention of enrolling first year students to the second year is 91.4%; this is higher than Ohio State University but lower than certain private research universities. Sixty percent of students graduate in four years; eighty percent of enrolling students graduate within six years. A senator asked why enrolling students don't persist to graduation. Dean Wolcowitz replied that they leave for many reasons. His staff contacts students who haven't registered one month after the deadline; and each of the assistant deans is assigned to a cohort of students to facilitate their regular contact with individual students.

Adjournment

Upon motion, duly seconded, the meeting was adjourned at 5:30 p.m.

APPROVED
by the
FACULTY SENATE

ELIZABETH H. WOYCZYNSKI
SECRETARY OF UNIVERSITY FACULTY

Stanton L. Gerson, MD
Director

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March 12, 2009

Alan Levine, MD
Professor of Medicine, Surgery, Pathology, and Pharmacology
Professor of Oncology, Case Comprehensive Cancer Center
Director of Surgical Research
Case Western Reserve University BRB 426
10900 Euclid Avenue
Cleveland, OH 44106-4952

Dr. Levine & Members of the CWRU Faculty Senate Graduate Education Review Committee:

Thank you for your review of the attached proposal for a new Certificate program Clinical Translational Oncology Research Scholars Program (CTORSP) in the School of Medicine and administered through the Case Comprehensive Cancer Center.

Moving forward with this Certificate program will allow us be compliant with an NIH requirement for career-development training grants. All institutions that are awarded a Paul Calabresi Career Development Award for Clinical Oncology (K12) are expected to receive formal recognition from the parent institution with a special certification in clinical research.

We look forward to the opportunity to discuss this Certificate proposal at your meeting on March 19th.

Sincerely,

Stanton L.Gerson, MD
Director, Clinical Translational Oncology Research Scholars Program (CTORSP)
Director, Case Comprehensive Cancer Center
Director, Ireland Cancer Center

CASE COMPREHENSIVE CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Clinical Translational Oncology Research Scholars Program (CTORSP)

The Clinical Translational Oncology Scholar's Program (CTORSP) is a 16-20 hour two-year program that culminates in a Certificate in Clinical Translational Oncology Research. This program has been developed to provide structured training for clinical oncology junior faculty who are interested in pursuing academic research careers as physician scientists. This training will address the need for clinician investigators to translate fundamental cancer research discoveries to medical care of cancer patients. Training will draw on the basic science and clinical investigators who are CWRU School of Medicine faculty and Case Comprehensive Cancer Center members.

The CTORSP will be directed by Stanton L. Gerson, MD, Professor of Medicine and Director of the Case Comprehensive Cancer Center (Case CCC) and Ireland Cancer Center, University Hospitals Case Medical Center (UHCMC) and Alvin H. Schmaier, MD, Professor of Medicine and Chief, Division of Hematology and Oncology, CWRU and UHCMC. CTORSP will be administered through the Case CCC in the School of Medicine. Margy Weinberg, MSW, Training Program Manager at the Case CCC, will serve as the administrator of the program.

Eligible CTORSP candidates are physicians (MD, DO or MD/PhD) with a clinical training background in one of the oncology disciplines, including medical, surgical, dermatological, pediatric, or radiation oncology. Eligibility and recruitment are detailed below. Up to five candidates will be accepted into the program every other year. The program will graduate up to five candidates every other year. This Certificate program combines individualized training plans with courses offered through the University. Each Scholar is guided by a mentoring committee in addition to a basic science and clinical mentor as described in the program details. The Scholars' individual training plan will consist of a formal didactic curriculum consisting of course work and longitudinal training addressing important topics in clinical research. In addition, each Scholar will design an hypothesis-driven, laboratory-based research that they will translate into a patient-oriented, clinical cancer trial. Their research will culminate in application for independent funding as a physician scientist.

Leadership, Faculty, and Resources

The CTORSP Certificate program will utilize the resources of nine outstanding interdisciplinary scientific programs within the Case CCC. These research programs bring together basic research scientists and clinical investigators from the three institutions of the Case CCC: CWRU, University Hospitals Case Medical Center (UHCMC), and Cleveland Clinic and include members from the other University-affiliated hospitals; MetroHealth Medical Center and the Louis Stokes Cleveland Veteran Affairs Medical Center. All of these institutions provide mentors who have strong cancer research programs and experience in clinical and research oncology training.

The program's Steering Committee will be composed of senior researchers selected by Drs. Gerson and Schmaier. The two primary mentors will work with the Scholar to select a mentoring committee. Together these clinicians and researchers will assist with developing the individualized training plan for each Scholar. Through formal meetings and presentations, the mentors and the program's Steering Committee will evaluate the Scholars' progress toward their research and training goals. Mentors and Steering Committee members are accomplished basic and physician scientists, with experience and success in achieving extramural support for their research.

PROGRAM DETAILS

1. Program Overview: The CTORSP Scholars select one of three areas of concentration: 1) Mechanism Based Therapeutic Development and Clinical Trials, 2) Stem Cell Biology and Hematologic Malignancy Clinical Trials, and 3) Prevention, Aging and Cancer Genetics and Clinical Trials. The Certificate program creates multiple opportunities for the Scholars to work with PhDs and MDs in order to establish transdisciplinary teams to develop an original cancer-related research project effectively carrying a laboratory observation through a clinical trial to improve an aspect of patient care. Scholars will be taught to make novel observations about the nature and progression of disease and to frame

questions that will stimulate their laboratory investigations that will become the basis for clinical investigations.

Each Scholar will be co-mentored by both a basic scientist and a clinical investigator. A mentoring committee comprised of faculty in the Scholar's focus of oncology research provides additional guidance and support. Mentors will be selected from one of nine scientific programs of the Case CCC. During the period of mentored laboratory training, the Scholars will develop original hypothesis-based experiments related to disease mechanisms at a molecular or cellular level. As the Scholars build on their laboratory conclusions to create and implement clinical trials, they will be mentored by clinical investigators. Clinical trials will be aimed at developing new methods for diagnosis and testing promising ideas for novel therapeutic interventions.

2. General Recruitment Strategies

The Steering Committee oversees, implements and monitors recruitment of Scholars. This responsibility includes assurance that the different clinical oncology disciplines are well represented. The specific recruitment strategies to assure a talented and diverse applicant pool are presented below in detail.

Scholar Candidate Eligibility

a. All candidates will be physicians holding the MD, DO or MD/PhD degrees and have completed specialty clinical training and are board-eligible in a cancer-related specialty. The Scholars will have a clinical training background in one of the following oncology disciplines: medical, surgical, dermatological, pediatric or radiation oncology.

b. All clinician candidates must be eligible to obtain NIH funding.

c. Clinician candidates who have equivalent training or clear experience in clinical trial design and leadership in clinical oncology trials would not normally be candidates for this Certificate program.

Scholar Candidate Pool

The primary source of candidates to this Certificate program will be junior faculty with primary or secondary CWRU appointments in the various fields of oncology. Candidates coming from existing clinical training programs corresponding to multiple oncology disciplines will also serve as an important applicant pool. These individuals will have training in oncology disciplines including surgery, gynecology, dermatology, medical, pediatrics and radiation oncology. For all candidates the Steering Committee will only accept candidates for review for whom their Department makes a minimum of a 2-year commitment so they can complete their Certificate program's requirements. The oncology disciplines with strong track records in recruiting and supporting research-oriented trainees are summarized as follows:

Medical Oncology Trainees: The fellowship program in Medical Oncology is under the direction of Dr. Alvin H. Schmaier, Chief of the Division of Hematology Oncology. The fellowship is approved for 5 years under ACGME. The fellowship program recruits 4-5 new trainees per year from a pool of 260 applicants of whom 30 are interviewed and 20 are ranked and placed in the fellowship ranking lottery between institutions. Applicants are selected on the basis of their promise as academic investigators.

Radiation Oncology Trainees: This Residency Program is approved under ACGME for 5 years. Over the last 4 years Radiation Oncology faculty has grown to include 12 physicians, 7 PhD medical physicists, and 6 PHD radiation biologists. NCI and other peer reviewed funding is approximately $3.5M.

Pediatric Oncology Trainees: The fellowship program in Pediatric Hematology/Oncology at Case and Rainbow Babies and Children's Hospital is under the direction of Dr. John Letterio, who served as Chief from the Carcinogenesis Branch of the NCI. Dr. Letterio has developed an academic division, recruited two physician scientists for laboratory-based research, and has established a 3-year fellowship for which the latter 2 years are research based.

3. Clinical Translational Oncology Research Certificate Program Details:

The Certificate program consists of three separate, yet integrated, sections: A) a formal didactic curriculum consisting of core course work and ongoing longitudinal training, B) an intensive mentored research project**,** and C) submission of an application for independent funding. Each of these components is described in detail below. Upon the successful completion of all program requirements, Scholars will receive a Certificate in Clinical Translational Oncology Research.

3A. FORMAL DIDACTIC CURRICULUM

3A1. COURSEWORK

3A1a. Required Courses

Translational Cancer Research (CNCR 501:1-4) (Fall & Spring for two years) Requirement: Attendance and participation at a minimum of 10 classes per year and presentation of research a total of 4 times over two years.

Translational Cancer Research (CNCR 501-1) (1 Fall) Course Directors: Stanton L. Gerson, MD & Alvin Schmaier, MD

> **Goal:** This section of the course teaches clinicians the language and concepts of translational research and provides opportunities for problem-solving and practical application to the student's individual research project. Topics: development of hypothesis and specific aims for original laboratory research question, developing and nurturing interdisciplinary collaborations, available resources through the Case CCC Core Facilities, understanding the regulatory environment governing research and learning the process of obtaining relevant approvals. Each student will write a sample hypothesis and specific aims which will be critiqued by the other members of the class. Pre-req: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

Translational Cancer Research (CNCR 501-2) (1 Sp) Course Director: Stanton L. Gerson, MD & Alvin Schmaier, MD

> **Goal:** This course teaches clinicians how to develop and manage a Phase I innovative cancer clinical trial. Topics: defining and designing the trial: 1) the purpose and parameters of the protocol, 2) incorporating laboratory research/ correlative science, 3) managing regulatory, legal, and ethical issues, 4) the purpose and process for the Letter of Intent (LOI), 5) choice of single or multi-site trials, 6) sample size calculations and how to accrue appropriate patient population, and 7) an introduction to the special statistical methods in the research design. Funding and budget issues: 1) attaining CTEP approval for therapeutic agents, 2) working with pharmaceutical companies, and 3) seeking NIH or foundation funding. Clinical trial management: 1) overseeing quality collection and management of data, 2) monitoring for evidence of adverse or beneficial treatment effects, 3) data analysis procedures, and 4) common mistakes. Additional topics: how to hire and supervise staff, and becoming involved with Eastern Cooperative Oncology Group (ECOG) or other Cooperative Groups. Each clinician will present his/her research twice during the semester. Pre-requisite: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

Translational Cancer Research (CNCR 501-3) (1 Fall) Course Director: Stanton Gerson, MD & Alvin Schmaier, MD

> **Goal:** This course teaches clinicians how to analyze and evaluate all aspects of the Phase I clinical trial including clinical results and findings. Topics: An introduction to the special statistical methods in the analysis of clinical trials based on the student's individual clinical trial design. Topics can include: intent-to-treat analysis, analysis of compliance data, equivalency testing, multiple comparisons, and sequential testing. Each Scholar will make a presentation explaining the progress they have made in writing their protocol through their attendance at the summer Clinical Protocol writing workshop. Pre-requisite: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

Translational Cancer Research (CNCR 501-4) (1 Sp) Course Director: Stanton L. Gerson, MD & Alvin Schmaier, MD

> **Goal:** Professional development. 1) This section of the course will focus on oral presentations with attention on the content and style of the presentation materials (PowerPoint), and oral presentation style. Each clinician will present his/her research twice during the semester. Written evaluation included. 2) This section of the course builds basic knowledge and develops core skills in scientific writing for peer reviewed journals, the anatomy of the scientific grant proposal, and how to serve as reviewer in the peer review process. 3) This section focuses on grantsmanship; sources of grant funding and strategies in applying and responding to reviews. 4) This section of the course teaches how to recognize and understand effective leadership traits

with interdisciplinary research teams in academic and clinic settings. Group discussion of article *Social Intelligence and the Biology of Leadership* by Goleman and Boyatzis; Topic 2: grantsmanship and the peer review process. Pre-requisite: Consent of Instructor. 6:00–7:45pm Wearn 137. Pass/No Pass.

In addition, Scholars will be required to take a special ethics course designed for clinical investigators. (If the Scholar shows proof of prior attendance at this or an equivalent course, this requirement is waived.)

Research Integrity and Ethics (IBMS 500) (0 Sum) Jessica Berg, PhD/Eric Juengst, PhD

Goal: To introduce students to the ethical, policy, and legal issues raised by research involving human subjects. Topics include (among others): regulation and monitoring of research; research in third-world nations; research with special populations; stem cell and genetic research; research to combat bioterrorism; scientific misconduct; conflicts of interest; commercialization and intellectual property; and the use of deception and placebos. IBMS 500 meets for 3 days in May.

3A1b. Elective Courses

(6 credit hours) Requirement: A minimum of one course must address clinical trial design. Courses must be taken for credit and completed during the two year program. Should the Scholar receive a fail or no pass, the Scholar is required to successfully repeat the course or receive a pass or a passing grade in an alternative course.

INTRODUCTORY COURSES

Theme: Clinical Trial Design

Introduction Clinical Research Summer Series (CRSP 401) (3 Summer) Douglas Einstadter, MD & E. Regis McFadden, MD

Goal: This course is designed to familiarize one with the language and concepts of clinical investigation and statistical computing, as well as provide opportunities for problem-solving and practical application of the information derived from the lectures. The material is organized along the internal logic of the research process, beginning with mechanisms of choosing a research question and moving into the information needed to design the protocol, implement it, analyze the findings, & draw and disseminate the conclusion(s). Regular Grading System.

Biostatistics for Clinical Research (CRSP 403) (3 Fall) Thomas Love, PhD

Goal: Learn the statistical process: how to conduct studies, what the results mean, and what can be inferred about the whole from pieces of information. Understanding and describing relationships between phenomena and measuring how well these relationships fit data. A project involves problem specification, data collection, management, analysis, and presentation. Will use statistical software extensively; exposed to multiple packages. Topics: descriptive statistics, exploratory data analysis, the fundamentals of probability, sampling, inferential statistics, power & sample size, experimental design, correlation, regression, & association. Prereq: CRSP 401. Regular Grading System.

Study Design and Epidemiology Methods (CRSP 402) (3 Fall) Douglas Einstadter, MD

Goal: Learn methods used in the conduct of epidemiologic and health services research; considers how epidemiologic studies may be designed to maximize etiologic inferences. Topics: measures of disease frequency, measures of effect, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, confounding, bias, and effect modification. Prereq: CRSP 401 or permission of instructor. Regular Grading System.

Health Disparities (CRSP 510) (3 Fall) Drs. Joseph J. Sudano and Ashwini Sehgal, and Michele E. Petrick

Goal: Provide theoretical and application tools for students from many disciplinary backgrounds to conduct research and develop interventions to reduce health disparities. The course is situated contextually within the historical record of the United States, reviewing social, political, economic,

cultural, legal, and ethical theories related to disparities in general, with a central focus on health disparities. Several frameworks regarding health disparities are used for investigating and discussing the empirical evidence on disparities among other subgroups (e.g., the poor, women, uninsured, disabled, and non-English speaking populations) are also included and discussed. Students are expected to develop a research proposal (observational, clinical, and/or intervention) rooted in their disciplinary background that incorporates materials from the various perspectives presented throughout the course, with the objective of developing and reinforcing a more comprehensive approach to current practices within their fields. Offered as CRSP 510, EPBI 510, MPHP 510, NURS 510, and SASS 510. Mon. 5:30– 8:00 pm, Location: NOA 31A. Regular Grading System.

Introduction to Behavioral Medicine (EPBI 411) (3 Fall) Kristina Noel Knight, MPH

Goal: Using a biopsychosocial perspective, students will learn the measurement and modeling of behavioral, social, psychological, and environmental factors related to disease prevention, disease management, and health promotion. EPBI 411 or MPHP 411. Tue/Thurs 1:15–2:30 pm, Loc: WHTE 324. Regular Grading System.

Theme: Communication and Leadership

Communication in Clinical Research (Part 1) (CRSP 412) (1 Fall) Drs. Ralph O'Brien and John J. Lewandowski

Goal: Parts 1 and 2 of this course build basic knowledge and develop core skills in scientific communication, grantsmanship, and the peer review process. Written and oral communication in clinical science, applying for grants, submitting abstracts and manuscripts, giving presentations, and the peer review process is covered. Recommended preparation: CRSP 401 or equivalent and consent of instructor. Mon 8:30–10:30am, Location: Cleveland Clinic JJ3-107 A & B. Pass/NoPass or Pass/Fail grading only.

Communication in Clinical Research (Part 2) (CRSP 413) (1 Sp) Ralph O'Brien, PhD

Goal: Parts 1 and 2 of this course build basic knowledge and develop core skills in scientific communication, grantsmanship, and the peer review process. Written and oral communication in clinical science, applying for grants, submitting abstracts and manuscripts, giving presentations, and the peer review process is covered. Prereq: CRSP 401 or equivalent and consent of instructor. Mon. 3:00 – 5:00 pm, Location: Cleveland Clinic, JJ3-107 A & B. Course offered for Pass/NoPass or Pass/Fail grading only.

ADVANCED

Theme: Clinical Trial Design

Statistics of Controlled Trials (EPBI 458) (3 Fall) Jeffrey Albert, PhD

Goal: Learn the special statistical methods and philosophical issues in the design and analysis of clinical trials. The emphasis is on practical important issues that are typically not covered in standard biostatistics courses. Topics include: randomization techniques, intent-to-treat analysis, analysis of compliance data, equivalency testing, surrogate endpoints, multiple comparisons, sequential testing, and Bayesian methods. Offered as EPBI 458 and MPHP 458. Tue/Thurs 1:15 – 2:30 pm, Location NOA 300. Regular Grading System.

Clinical Trials and Intervention Studies (EPBI 450) (3) Mark Schluchter, PhD

Goal: Learn issues in the design, organization, and operation of randomized, controlled clinical trials and intervention studies. Emphasis on long-term multicenter trials. Topics include legal and ethical issues in the design; application of concepts of controls, masking, and randomization; steps required for quality data collection; monitoring for evidence of adverse or beneficial treatment effects; elements of organizational structure; sample size calculations and data analysis procedures; and common mistakes. Prereq: EPBI 431 or consent of instructor. XLIST: MPHP 450, Mon/Wed 1:30 – 2:45, Location: MEDS WG73. Regular Grading System.

Observational Studies (CRSP 500) (3 Sp) Thomas Love, PhD

An observation study is an empirical investigation of treatments, policies or exposures and the effects that they cause, but it differs from an experiment because the investigator cannot control treatment assignment. **Goal:** Learn design, data collection and analysis methods appropriate for clinical investigators, preparing students to design and interpret their own studies, and those of others in their field. Technical formalities are minimized, and the presentations focus on the practical application of methodologies and strategies. A course project involves the completion of an observational study, and substantial use of statistical software. Topics include randomized experiments and how they differ from observational studies, planning and design for observational studies, adjustments for overt bias, sensitivity analysis, methods for detecting hidden bias, and propensity methods for selection bias adjustment, including multivariate matching, stratification and regression adjustments. Prereq: EPBI 432, EPBI 441, CRSP 406 or consent of instructor. Tue/Thurs 9:00–11:30am, Location: MetroHealth. Regular Grading System.

Theme: Bioinformatics

Introduction to SAS Programming (CRSP 406) (2 Fall) Rhoderick Machekano, PhD and Steven Lewis, MS

Goal: Students learn how to use SAS version 8.2 in the context of clinical research. Topics include an overview of the SAS "data step" and procedures commonly used to explore, visualize, and summarize clinical data. Students learn the basics of the SAS programming language, how to troubleshoot SAS code, as well as how to interpret selected SAS output. Clinical research datasets are used in class examples, computer laboratory sessions, and homework. Each session includes a lecture immediately followed by a computer lab to reinforce the concepts introduced. Students work in small groups or individually. Recommended preparation: CRSP 403 or consent of instructor. Tues/Thurs 8:30–11:00am, Location: MetroHealth, Rammelkamp, Rm R219, Course offered for Pass/NoPass or Pass/Fail grading only.

Logistic Regression/ Survival Analysis (CRSP 407) (3 Sp) Denise Babineau, PhD

Goal: Learn how to use the two most common statistical modeling techniques found in the medical, epidemiologic, and public health research fields; logistic regression and survival analysis. The course emphasizes summarizing and analyzing binary and time-to-event outcomes. The focus is on establishing a foundation for when and how to use these modeling techniques as well as an understanding of interpreting results from analyses. Two course projects will involve problem specification, data collection, analysis, and presentation. Students use statistical software extensively and are exposed to output from SAS. Planned topics include contingency tables, logistic regression models and diagnostic measure, analyzing ordinal outcomes, estimating of the survival curve, Cox proportional hazard regression models and diagnostic measures, and sample size estimation. Prereq: CRSP 403, CRSP 406 or consent of instructor. Mon 1:00–2:30; Wed 3:30–5:00pm. Regular Grading System.

The Biology and Mathematics of Biochemistry Microarray Studies (BIOC 460) (3 Sp) Patrick Leahy, PhD

Goal: This is a hands-on computer-based course, which upon completion will enable participants to conduct meaningful analyses of expression microarray and proteomics data. The course is multi-faceted and cross-disciplinary in nature. Upon completion, participants will have a thorough understanding of the principles underlying available micro-array technologies, including: sample preparation, sample processing on microarrays, familiarity with the use of Affymetrix Expression Console software, generation of microarray data sets, an ability to move data effortlessly from EC MS Excel and from there into MS Access in order to trim, query and globally manipulate and pre package data. Importation of data into other third party software such as, GeneSpring (Agilent), DecisionSite (Spotfire) and PathwayStudio (Ariadne, Genomics) will enable participants to cluster and mine the data in search of higher-order patterns and pathway annotation and assignment. A new module on proteomics and introduction to systems Biology has been added this year. Permission from course co-ordinator required. Payment of Lab fee ($600). Regular Grading System.

Theme: Communication and Leadership

Working in Interdisciplinary Research Teams (CRSP 501) (1 Fall) Shirley Mason Moore, PhD, RN, FAAN

Goal: Understand why and how different professional disciplines, each representing a body of scientific knowledge, must work together to develop and disseminate knowledge. Learners develop a set of skills specific to being an effective member and leader of an interdisciplinary research team, including working with different value and knowledge sets across disciplines, running effective meetings, managing conflict, giving and receiving feedback, and group decision-making techniques. Using the small group seminar approach and case studies, learners practice individual and group communication, reflective and self-assessment techniques, and engage in experiential learning activities regarding effective teamwork in interdisciplinary research teams. Techniques to increase group creativity and frame new insights are discussed. Prereq: K12 Appointment or permission of instructor. Fri 9:00am–3:00pm, S 8:00am–3:00pm, Location: NOA 228, Course offered: Pass/No Pass or Pass/Fail grading only.

Leadership Assessment and Development (CRSP 502) (2 Sp) Tony Lingham, PhD

Goal: Learn a method for assessing their knowledge, abilities, and values relevant to management; and for developing and implementing plans for acquiring new management related knowledge and abilities. The major goals of this course include generating data through a variety of assessment methods designed to reveal your interests, abilities, values, and knowledge related to leadership effectiveness; learning how to interpret this assessment data and use it to design/plan developmental activities; small group sharing of insights from the various assessments. Prereq: K12 appointment. Tue1:00–4:00 pm. Regular Grading System.

Innovation and Entrepreneurship (CRSP 503) (2 Sp) Scott Shane, PhD

Goal: Acquaint and ultimately engage clinical researchers with the business of innovation and entrepreneurship. Goals include: (1) to provide researchers with many of the skills that they would need to translate academic research into commercial uses; (2) to sensitize clinical researchers to the goals of the business community and facilitate their ability to work with the private sector on technology development; and (3) to make clinical researchers aware of the processes of academic technology development and transfer. Sessions consist of lectures and case discussion facilitated by the instructor. Some sessions include members of the business community as guest lecturers. As an example, students discuss the financing of new companies with local venture capitalists. Student products include the evaluation of the commercial potential of a university technology in which they apply their new knowledge about commercialization of scientific discoveries. ECON 406, HSMC 406. Prereq: Consent of instructor. Wed 1:00 – 2:45 pm, Location: PBLB 121. Regular Grading System.

3A2. LONGITUDINAL TRAINING

Formal coursework supplemented by longitudinal training provided through seminars, meetings, conferences and retreats, as well as institutional conferences, which will allow the Scholar to have interaction with their peers, colleagues, and mentors.

3A2a. Protocol Review & Monitoring Committee (PRMC), Chair, David Adelstein, MD

Purpose: Observe and participate in PRMC deliberations. This committee provides the scientific review required for all cancer related human subject research prior to IRB review. 2nd/4th Tues/Wearn 137, 4:30-6:00PM.

3A2b. Clinical Trial Protocol Development: Each Scholar will make a presentation during the Translational Cancer Research (Fall CNCR 501-3) detailing the progress and skills they have acquired through participation in one of the following Clinical Protocol Writing workshops.

American Society of Clinical Oncology and American Association for Cancer Research - Methods in Clinical Cancer Research **http://www.vailworkshop.org/.**

A 7-day intensive workshop in the essentials of effective clinical trial designs of therapeutic interventions in the treatment of cancer for junior faculty clinical researchers. AACR and ASCO have designed this intensive Workshop to increase the reliability and effectiveness of clinical trials by:

Introducing clinical fellows and junior faculty with an oncology subspecialty to the principles of good clinical trial design. **Goal:** This Workshop will give them the tools they need to conduct clinical trials that will yield clear results that investigators can use to proceed to the next level of research. **Goal:** Exposing early career clinical scientists to the full spectrum of challenges in clinical research – from surgery, radiotherapy, conventional and investigational antineoplastic agents and multidisciplinary treatment regimens to gene therapy, biologic therapy, and multimodality and combination treatments. Workshop faculty seek to inspire participants to devote all or a portion of their future careers to some aspect of clinical research. **Goal:** Developing a cadre of well-trained, experienced clinical researchers whose expertise will foster better clinical trial design. **Goal:** Learn such expertise to thereby hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

The American Society of Hematology: Clinical Research Training Institute Curriculum http://www.hematology.org/education/training/crti_brochure_2008.pdf

3-part program: summer workshop, a week-long immersion course in the basics of clinical research. Participants work from their own proposed clinical research protocols and refine and revise their plans with input from the expert faculty. Two subsequent sessions, one at the ASH annual meeting and one in the spring, provide an opportunity for further interaction and mentoring opportunities.

Participants will:

Discuss the principles of clinical research design and execution

Examine the methodology for interpreting results of clinical research studies

Detail the ethical and regulatory issues of clinical research, emphasizing human research protection

Discuss the fundamentals of competitive grant writing, abstract presentation, & manuscript preparation

Further develop & improve the quality of their own research proposals through input from faculty & peers

Learn strategies for pursuing and developing a successful career in hematologic research

Meet leaders in clinical hematologic research who can enhance networking opportunities for career development

3A2c. Clinical Trials Disease Teams pre-review all therapeutic trials for scientific merit, prioritization, and intent to accrue patients.

Goal: Through observation and participation in these meetings Scholars will gain an appreciation of the methods by which the clinical research agenda is developed within the disease teams.

Clinical Trials Disease Teams	**Leaders**
Brain Tumors	Andrew Sloan, MD, Gene Barnett, MD
Head and Neck Cancer	Panos Savvides, MD, David Adelstein, MD
Thoracic/Esophagus Cancers	Afshin Dowlati, MD, Tarek Mekhai, MD
Breast Cancer	Joseph Baar, MD, G.Thomas Budd, MD
Gastrointestinal Cancer	Smitha Krishnamurthi, MD, Robert Pelley, MD
Genitourinary Cancer	Matthew Cooney, MD, Robert Dreicer, MD
Gynecologic Cancer	Steven Waggoner, MD, Peter Rose, MD
Malignant Melanoma	Kevin Cooper, MD, Ernest Borden, MD
Soft Tissue Sarcoma	Patrick Getty, MD, G. Thomas Budd, MD

Lymphoma, Hematologic Malignancies/ Stem Cell Transplant, Myeloma, Leukemia	Hillard Lazarus, MD, John Sweetenham, MD
Pediatric Malignancies	John Letterio,MD, Gregory Plautz, MD
Phase I Program	Afshin Dowlati, MD

3A2d. Designated Tumor Board Conference

Goals: The Tumor Board Conferences bring together multidisciplinary team to evaluate the diagnosis, classify the stages, discuss management modalities and selection of treatment modalities of various cancers.

Conference	Directors	Day	Time
Thoracic	Afshin Dowlati, MD	Monday	7:00-8:30AM
Sarcoma	Patrick Getty, MD	2nd/4th Monday	5:00-6:00PM
GU	Matt Cooney, MD	Tuesday	7:00-8:00AM
Neuro/Gamma Knife	Robert Maciunas, MD	Wednesday	1:30-2:30PM
GI	Thomas Stellato, MD	Wednesday	4:30-5:30PM
Lymphoma/Leukemia	Brenda Cooper, MD	Thursday	8:00-9:00AM
Breast	Paula Silverman, MD	Thursday	4:00-6:00PM
Head/Neck	Panos Savvides, MD/PhD, Pierre Lavertu, MD	Friday	7:00-8:00AM

All conferences are held in the Radiation Oncology Conf Room, Lerner Tower (B-151)

3A2e. Institutional Conferences:

Goals: Provide an opportunity for multidisciplinary cancer focused clinicians & researchers to be introduced to research discoveries and treatment modalities from peers, national and international experts in their fields

Conference	Day/Location	Time
Ireland Cancer Center Grand Rounds	Wednesday/Lerner B-151	8:00-9:00AM
Cancer Center Blood Club Seminar	Friday/BRB 105	12:00-1:00PM
Hematology/Oncology Fellows Conference	Friday/Wearn 137	8:00-9:00AM
Pathology Grand Rounds	2nd Wed Sept.-June/Pathology Amp	8:00-9:00AM
Research and Progress	Monday/WRB 2-136	12:00-1:00PM
Hematology Conference	Wednesday/WRB 2-136	1:00-2:00PM

3A2f. Case Comprehensive Cancer Center Annual Retreat (Held for 2 days each July)

Goals: 1) To interact and network with Case Cancer Center members, 2) to learn first hand about individual member's current and future cancer research with the possibility of creating collaborations, and 3) develop a finer understanding of the resources available through the Case Cancer Center.

3B. INTENSIVE MENTORED RESEARCH PROJECT (10 credit hours)

In addition to the core courses and longitudinal training described above, each Scholar will participate in an intensive mentored research project centered on a specific hypothesis-based research problem that will result in a clinical trial and a first authored publication in a peer-reviewed journal. This program will include twice-yearly mentoring committee meetings and a review of a minimum of one manuscript for a journal.

3B1. Primary Co-Mentors and Mentoring Committee

Each Scholar will be guided in choosing two primary co-mentors along with a mentoring committee consisting of specialists in the Scholar's field of oncology research. One mentor represents a clinical oncology discipline (medical, surgical, dermatological, pediatric, or radiation oncology); and a

second mentor represents a basic or prevention/ population science discipline (cancer genetics, cancer biology, clinical pharmacology, epidemiology, and health care outcomes). This pairing of clinical and basic investigators as primary co-mentors fosters a complementary interdisciplinary clinical and basic training experience that involves the hands-on exposure to translational research projects involving the clinician and basic scientist. Early in the first year, Scholars, in consultation with their mentors, will develop an individualized plan which will identify their current level of learning in key areas for review as well as identify areas for future development. Together, they will identify key learning objectives, the means for meeting them and a timeline for completion of the certificate requirements. At this point, Scholars also identify various sources of learning appropriate to identified short and long-term career goals (including research scope, clinical trial plans, manuscript preparation and timeline for the Certificate program requirements), and learning needs essential to achieving their goals. Scholars will meet, on an ongoing basis, with their primary co-mentors and a minimum of twice a year with their mentoring committee, which includes Dr. Alvin H. Schmaier. Dr. Schmaier will have oversight of the mentoring committees for each Scholar.

The goal of the mentoring committee is to provide a mentoring that focuses on developing the skills necessary for translating basic cancer research findings into clinical experiments, procedures, and trials directly involving cancer patients in a clinical environment. This includes an understanding and working knowledge of the scientific method, particularly hypothesis development, experimental design, and statistical methods. Further, the clinical mentoring relationship will provide the Scholar with clinical research skills that will deal directly with aspects of cancer detection, diagnosis, prognosis, or treatment, experience and instruction in how to interact and communicate with basic research scientists in the design and implementation of collaborative translational research involving patients. In this context, basic scientists are involved in the training program in clinical seminars, protocol planning sessions, and interdisciplinary program working groups.

Oversight for this portion will be achieved through presentations of research progress. This will occur via poster or PowerPoint presentations to peers as well the twice-yearly mentoring committee meeting that includes feedback/recommendations on their research/clinical trials/publications/grant submission progress and annual progress report given as PowerPoint presentation at the Steering Committee meeting. Drs. Stanton Gerson and Alvin Schmaier will also monitor the Scholar's progress at the monthly Translational Cancer Research course including during their PowerPoint presentations of their progress at this course. In addition, Margy Weinberg will oversee the Scholar's registration to national oncology meetings; organize the CNCR 501 Translational Cancer Research course, the Steering Committee Annual Evaluation; and schedule the Scholar's PowerPoint presentations.

3B2. Faculty Mentors and Thematic Research Focus Areas

All scientific programs of the Case CCC will contribute mentors and provide a scientific focus area of investigation for the Scholar. This allows for the co-ordination of multidisciplinary and transdisciplinary investigation into the training and research focus of the Scholars in a manner that cuts across the Scientific Programs of the Case CCC. All clinical research mentors are involved in investigator-initiated clinical trials, have outside funding for clinical research, and participate in Case CCC multidisciplinary research initiatives. They will provide Scholars with training in clinical trial hypothesis testing through study design, including involvement by the biostatisticians, patient eligibility and ethical conduct during early phase clinical trials, patient accrual and assessment in the conduct of the interventional trial and careful review of the endpoints of the trial. Basic research mentors have successful and accomplished laboratory or prevention and interventional programs that will provide the framework for the Scholar to develop hypotheses that form the basis for interventional clinical trials.

Case CCC Scientific Programs and Clinical Trials Disease Teams	
Program	**Leaders**
Cancer Genetics	Sanford D. Markowitz, MD, PhD* Professor of Medicine (Hematology/Oncology) Robert C. Elston, PhD* Professor of Epidemiology & Biostatistics

Cell Death Regulation	Clark W. Distelhorst, MD* Professor of Medicine (Hematology/Oncology) & Pharmacology Nancy L. Oleinick, PhD* Professor of Radiation Oncology Alexandru Almasan, PhD Associate Professor of Cancer Biology, Radiation Oncology
Molecular Basis of Cancer	George R. Stark, PhD Professor of Molecular Genetics Susann M. Brady-Kalnay, PhD Associate Professor of Molecular Biology & Microbiology
GU Malignancies	Eric A. Klein, MD* Professor of Urology Warren D.W. Heston, PhD Professor of Cancer Biology, Urology
Stem Cells & Hematologic Malignancies	Kevin D. Bunting, PhD* Associate Professor of Medicine (Hematology/Oncology) Hillard M. Lazarus, MD* Professor of Medicine (Hematology/Oncology)
Developmental Therapeutics	Afshin Dowlati, MD* Associate Professor of Medicine (Hematology/Oncology)
Cancer Prevention, Control, & Population Research	Gregory S. Cooper, MD* Professor of Medicine (Gastroenterology) Susan A. Flocke, PhD* Associate Professor of Family Medicine
Aging-Cancer Research	Nathan A. Berger, MD* Director, Center for Science, Health and Society Hanna-Payne Professor of Experimental Medicine Julia Hannum Rose, PhD Professor of Medicine (Geriatrics)
Cancer Imaging (Developing Program)	James Basilion, PhD Associate Professor of Radiology, Biomedical Engineering Jeffrey L. Duerk, PhD Professor of Radiology, Biomedical Engineering
Clinical Disease Teams	**Leaders**
Brain Tumors	Andrew Sloan, MD*, Gene Barnett, MD
Head and Neck Cancer	Panos Savvides, MD, David Adelstein, MD
Thoracic/Esophagus Cancers	Afshin Dowlati, MD*, Tarek Mekhai, MD
Breast Cancer	Joseph Baar, MD, G.Thomas Budd, MD
Gastrointestinal Cancer	Smitha Krishnamurthi, MD, Robert Pelley, MD
Genitourinary Cancer	Matthew Cooney, MD, Robert Dreicer, MD
Gynecologic Cancer	Steven Waggoner, MD*, Peter Rose, MD
Malignant Melanoma	Kevin Cooper, MD*, Ernest Borden, MD
Soft Tissue Sarcoma	Patrick Getty, MD, G. Thomas Budd, MD
Lymphoma, Hematologic Malignancies/ Stem Cell Transplant, Myeloma, Leukemia	Hillard Lazarus, MD*, John Sweetenham, MD
Pediatric Malignancies	John Letterio, MD*, Gregory Plautz, MD
Phase I Program	Afshin Dowlati, MD*

***Serves as a mentor or on the Certificate Steering Committee**

3C. Applications for Independent Funding

In the 1st year of the program, Scholars will be encouraged to apply for additional research support funding to support their clinical trials. Resources include ACS, Leukemia and Lymphoma Foundation and pharmaceutical companies. During the 2nd year in the program, Scholars will be required to submit applications for funding to such sources as: NIH K22 Career Transition Award, NIH K23 Mentored Patient Oriented Research Career Development Award or Independent awards such as R01 or R03. Oversight for this component will be accomplished, in part, through the mentors who will be involved in the review of their Scholar's grant submissions. Further, Drs. Gerson and Schmaier will discuss grant submissions during the Translational Research Course. Applications for funding are listed in the annual progress report that is reviewed by the Steering Committee.

3D. Overview and Timeline Of Certificate Requirements

	Requirements	Details	Credit Hours	Timeline	Product
A	**Formal didactic curriculum**	1. CNCR 501(1-4)- Translational Cancer Research	4 hrs	1. 1st Wed eve. both yrs	1. Passing grade on presentation to CNCR 501 directors/students & to Steering Committee, credit for 4 courses
		2. IBMS 500 Research Integrity & Ethics	0 hrs	2. 3 days in May/ 2nd yr	2. Transcript
		3. Two courses; 6 hrs from list of courses in section A.	6 hrs	3. Anytime during 2yrs	3. 6 hours credit, course required projects
		4. Protocol Review Monitoring Committee		4. Longitudinal	4. Presentation of IRB proposal
		5. ASCO/AACR or ASH Protocol Writing Course		5. Summer 2nd yr	5. Presentation of protocol at CNCR 501
		6. Clinical Disease Teams		6. Longitudinal	6. Presentation of LOI
		7. Designated Tumor Board: Thoracic, Sarcoma, GU, Neuro/Gamma Knife, GI, Lymphoma/Leukemia, Breast, or Head/Neck		7. Longitudinal	7. Active participation
		8. Institutional Conferences: Ireland Cancer Center Grand Rounds, Cancer Center Blood Club Seminar, Hematology Conference, Hematology/Oncology Fellows Conference, Pathology Grand Rounds, Research and Progress		8. Longitudinal	8. Presentation when requested
		9. Case Comprehensive Cancer Center Retreat		9. July/2 days annually	9. Presentation or poster when requested.
B	**Intensive mentored research project**	1. Laboratory cancer related research	10 hrs	1. Primarily 1st yr	1. Develop original hypothesis & specific aims
		2. Developmental Therapeutics Program Meetings		2. Longitudinal	3. From concept to successfully opening a clinical trial
		3. Developmental Therapeutic Clinical Trial		3. 1st & 2nd yr	4. Passing grade in research presentation in CNCR 501& Steering Committee meeting
		4. Mentoring committee meetings		4. Twice a yr	4. Summary of meeting & annual progress report
				5. Publication in either yr	5. 1st author publication in peer reviewed journal
				6. Review of manuscript anytime during 2 years	6. Review of at least 1 manuscript for national

					journal
C	**Application for independent funding**	1. Fellowships: ie ACS, LLF 2. Pharmaceutical companies 3. R or K grant-mentored or independent career awards	0	1. & 2. During 1st yr 3. During 2nd yr	1-3. Written application for funding submitted to SC for review

***** *If the Scholar shows proof of prior attendance at either of these or an equivalent course, this requirement is waived.)*

CLINICAL TRANSLATIONAL ONCOLOGY RESEARCH CERTIFICATE PROGRAM
CORE COMPETENCIES

Competency 1: Develop a rational scientific hypothesis based on clinical knowledge and research findings with the potential for improving the medical care of cancer patients	
1.1	Develop an understanding of cross disciplinary concepts and language in order to develop original cancer research hypothesizes
1.2	Demonstrate ability to communicate, verbally and in writing, with basic and behavioral research scientists (PhD) in order to effect the translation of basic/behavioral information into patient-oriented research
1.3	Demonstrate the ability to formulate specific aims to validate the research hypothesis
1.4	Identify Case Comprehensive Cancer Center Core Facility resources available to support and enhance the implementation of the scientific research (Biostatistics, Gene Expression & Genotyping, Imaging Research, Tissue Procurement and Histology)
1.5	Attain required research subject approval(s) to conduct laboratory based research, if appropriate
1.6	Demonstrate the ability to translate laboratory-based scientific knowledge into a developmental therapeutic cancer clinical trial
1.7	Demonstrate an understanding of, and the ability to manage, ethical issues that may arise during the course of the study
Competency 2: Develop, conduct, manage and evaluate the results of an innovative cancer clinical trial	
2.1	Translate basic research findings into an innovative clinical trial designed to improve the medical care of cancer patients
2.2	Identify Case Comprehensive Cancer Center Core Facility resources available to support and enhance the implementation of the cancer clinical trial (Clinical Trials, Biostatistics, Translational Research, Cancer Pharmacology)
2.3	Demonstrate an understanding of the principles involved in producing an accepted Letter of Intent (LOI)
2.4	Attain Cancer Therapy Evaluation Program (CTEP) approval (when appropriate) for utilization of the selected therapeutic agent
2.5	Attain required Institutional Review Board (IRB) approval to perform the clinical trial
2.6	Accrue the appropriate patient population necessary to perform the desired clinical trial
2.7	Oversee data collection and management of clinical results and findings
2.8	Analyze clinical results and finding
2.9	Critically evaluate all aspects pertaining to the clinical trial
2.10	Demonstrate an understanding of, and the ability to manage, ethical issues that may arise during the course of the clinical trial
Competency 3: Develop and nurture transdisciplinary collaborations	
3.1	Work with a mentoring team to identify and initiate potential professional collaborations
3.2	Identify potential collaborations opportunities with other Scholars in the certificate program
3.3	Establish an effective relationship with various scientific (PhD), clinical (oncology disciplines), and program leadership within the certificate program
3.4	Identify a potential network of collaborations locally (Cleveland), regionally (Ohio and Tri-State),

	nationally, and internationally (when appropriate) to enhance future cancer based research
3.5	Identify and utilize (when appropriate) resources available through the Eastern Cooperative Oncology Group (ECOG)
3.6	Demonstrate effective relationships with CTEP, IRB and other regulatory agencies to aid in the advancement of the proposed clinical trial
3.7	Develop and nurture productive collaborations
Competency 4: Recognize and understand effective leadership traits	
4.1	Actively participate in appropriate clinical and scientific based workshops, seminars, retreats, and other learning opportunities
4.2	Establish an effective relationship mentors, mentoring committee members, and colleagues.
4.3	Demonstrate the ability to effectively provide constructive feedback and receive criticism
4.4	Recognize effective and ineffective leadership traits
Competency 5: Demonstrate ability to disseminate, in both oral and written form, the key scientific foundations and the clinical findings	
5.1	Acceptance to present their original cancer research findings at a nation oncology conference
5.2	Acceptance of a first authored research manuscript to a peer reviewed journal
5.3	Submission of a grant proposal with clear specific aims
5.4	Review and edit a manuscript for a national journal
5.5	Demonstrate the ability to translate data from the laboratory setting to the clinical setting and back to the laboratory (bench-bedside-bench)

4. INTERACTION BETWEEN THE CERTIFICATE PROGRAM AND OTHER PROGRAMS:

4A. CTSC

The Certificate program will take advantage of resources available through the School of Medicine's Clinical Translational Science Center, through their programs for research and career development of junior faculty. Both the Certificate and the CTSC programs take advantage of the courses offered through the CRSP.

4B. CRSP (The Masters in Clinical Research Program):

The Masters in Clinical Research Program (CRSP) will review courses and research proposals in order to decide on an individual basis which of the credits, presented here, can be transferred to CRSP Master Program.

5. PROGRAM OVERSIGHT, ADDITIONAL RESOURCES, AND EVALUATION

5A. Program Oversight

Dr. Gerson, Director of the Case CCC, will serve as the Program Director of the Certificate Program. Dr. Gerson will be responsible for the oversight of the CTORSP training program, including appointment of mentors, decisions regarding the curriculum, and implementation of Steering Committee recommendations. He will oversee and promote high quality mentoring of clinical investigators and will support their multidisciplinary training by taking advantage of all of the resources of the Case CCC. Dr. Gerson's career interests reflect the goals of the Certificate Program and his status as Program Director ensures the seamless linkage to the Cancer Center and the commitment by the Cancer Center to the goals of the Certificate Program.

Dr. Schmaier, Chief of the Division of Hematology Oncology, serves as the Co-Director. Dr. Schmaier is an outstanding laboratory-based investigator, an excellent clinician and has an extensive track record mentoring students, fellows and junior faculty. As Certificate Program Co-Director, Dr. Schmaier will have oversight of the mentoring committees for each Scholar and will co-chair the Steering Committee.

5B. Additional Resources

5B1. Shared Resources

As part of the Case CCC, Scholars will have access to the expertise and services of the Case CCC Shared Resources to aid in their training and to advance their research goals. The resources are described, briefly, below.

Shared Resources of the Case Comprehensive Cancer Center

Shared Resource	Leadership	Description
Athymic Animal & Xenograft	Lili Liu, PhD	Preparation of mouse xenografts for drug screening and immunodeficient animals for human stem cell engraftment.
Behavioral Measurement	Susan Flocke, PhD	Measure development and resource for analysis of human responses.
Biostatistics	Mark Schluchter, PhD	Support for clinical trials and preclinical data analysis.
Cancer Pharmacology	Yan Xu, MD	Detection methods development and pharmacokinetic measurements during clinical trials.
Clinical Trials	Smitha Krishnamurthi, MD	Management of all investigator-initiated clinical trials.
Confocal Microscopy	James Jacobberger, PhD	High quality microscopic analysis.
Cytometry	James Jacobberger, PhD	Flow analysis of cell phenotype, apoptosis, cell cycle, and drug effect of TK inhibitors.
Gene Expression & Genotyping	Martina Veigl, PhD	Affymetrix chips for gene expression, SNIPS, genome scanning to clinical samples.
Hematopoietic Stem Cells	Luis Solchaga, PhD	Analysis of stem cells, distribution of hematologic malignancies cell samples.
High Throughput Sequencing	Mark Adams, PhD	High throughput sequencing Examination of genetic alterations associated with clinical and experimental cancers
Hybridoma	Clemencia Colmenares, PhD	Preparation of antibodies.
Imaging Research	Christopher Flask, PhD	Animal and human imaging with MR, PET, luciferace, SPECT, imaging and radionuclide preparation.
Practice Based Research Network	James Werner, PhD	130 practice network in Northern Ohio for analysis of practice trends and interventions in cancer screening and prevention.
Proteomics	Mark Chance, PhD	Mass spectrometry and peptide identification.
Radiation Resources	Nancy Oleinick, PhD	Research equipment for radiation of animals and cell lines.
Tissue Procurement & Histology	Gregory MacLennan, MD	Collection and distribution of human tumors discarded at surgery.
Tissue Biorepository	Joseph Willis, MD	Preparation of tissue specific biorepository with clinical outcome annotation.
Transgenic & Targeting	Ronald A. Conlon, PhD	Creation of transgenic and knockout mice.
Translational Research	John J. Pink, PhD	Coordinating center for collection, processing, storage and distribution of

		human samples from clinical trials.

5B2. Special Training Environment

There are a number of specific training sessions for this program. All involve active working groups and scientific collaborating teams that meet regularly to review results, develop new concepts, review clinical trials based on laboratory efforts and manage patients on early phase clinical trials. The specific scheduled meetings are:

Drug Development Working Group Committee monthly meeting (Monday 4-6 pm). All laboratory and clinical investigators involved in development of novel anti cancer drugs either in preclinical or early phase clinical trials including laboratory correlates evaluated during early clinical development of new drugs attend this meeting.

Included are pharmacokinetics of clinical drugs with methods development and validation for new agents; pharmacodynamic measurements of targets, enzyme, protein, DNA damage, cell cycle analysis, and apoptosis, depending on the agent, using biochemical cytometry, IHC, and imaging technologies; and preclinical evaluation of new markers to be used in clinical trials.

Angiogenesis Working Group (monthly, Wednesday, noon): This team evaluates new molecules that have anti-angiogenic properties in cancer, develops research and clinical questions involving basic biologists in the Vascular Biology of Cancer initiative, the imaging research group and the clinical trials group.

Phase I Patient Protocol Review (Friday, 9-11 am). This weekly meeting reviews all active patients on Phase I clinical trials at Case CCC. New trials, adverse events, dose escalation, regulatory, safety and privacy issues are addressed. Scholars develop clinical protocols with mentors and seek input from the Translational Core Facility (John Pink, PhD, Director) and from laboratory investigators. Statisticians from the Cancer Center Biostatistics Core are actively involved in study design and post-activation study review and analysis.

Developmental Therapeutics Program Meetings (Wednesday 5-60 pm) This weekly meeting will aid Scholars in the understanding the development and prioritization of clinical trials, and promote the discovery and evaluation of new mechanism-based therapeutics for the cancer patient. Program investigators lead innovative Phase I and Phase II clinical trials with novel agents, incorporating pharmacokinetic and pharmacodynamic studies to monitor drug effects, and to develop relevant biomarkers by integrating correlative laboratory endpoints and capitalizing on cancer imaging technologies.

5C. Program Evaluation

5C1. Evaluation of Mentoring: Mentors and Scholars

Mentoring is regarded as a powerful catalyst and essential for professional development, and is considered critical for establishing a strong career in clinical research and academic medicine. Evaluations will assess the extent to which Scholars and their mentors identify and meet expectations within the mentor-scholar relationship; the extent to which short- and long-term career goals are set; and whether scholars participate in close, collaborative relationships with their mentors. Special attention will be given to the extent to which women and minorities are supported in the mentoring relationship; to the assessment of issues in such areas as gender and power; negotiation and conflict management; performance pressures, isolation, and role-limiting expectations. Both surveys and individual interviews will be used to assess the quality of the mentoring relationships.

5C2. Steering Committee and Evaluation

The Steering Committee will have a very active role evaluating the Certificate program, providing feedback on mentor and Scholar interactions and will serve as the central review during the evaluation of scholars, mentors, and the Certificate program. The Steering Committee will review each Scholar's progress on a yearly basis. At this annual meeting Scholars will provide a PowerPoint presentation outlining their research progress and advancement in the Certificate program according to the goals and established timeline. The Steering Committee will review the Scholar's evaluation of their

mentors and Certificate program and the mentor's evaluation of the Scholar's progress and the Certificate program. The mentoring committee issues an evaluation on a yearly basis or more frequently, if the mentoring committee report raises concerns. This process is longitudinal and continuous over the course of the training period. The goal is to assure that Scholars are developing the skills and confidence to design and manage clinical trials; to fine tune the didactic training to meet current and future needs; and successfully apply for independent funding.

5C3. Evaluation Process and Results

The continued evolution of the Certificate program keeps it current with mentor and Scholar expectations and needs. A core value of the CTORSP is that regular assessment of all elements of the program is essential to its continued evolution. The input of Steering Committee members and research mentors is sought as well as the evaluations of the Scholars themselves, so that programs may be tailored to the Scholars needs and interests.

5C4. Tracking

For tracking purposes, a variety of data regarding applicants and selected Scholars will be collected and reviewed yearly with the Steering Committee. These outcomes, tracked and recorded in a database, will include: 1) all scholars who applied for admission or positions within the department(s) participating in the Program; 2) scholars who were offered admission to or a position within the participating department(s); 3) scholars actually enrolled in the participating departments; 4) applicant characteristics (i.e., degree, gender, ethnicity, prior institution, topic of research); 5) information on the recruitment and retention of underrepresented minorities will be collected.

In addition, in order to monitor and evaluate the Certificate Program and Scholars' performance in the longer term, Scholars' perceptions of program quality and impact, as well as specific outcomes consistent with the goals of this program, will be measured annually from matriculation and up to 7 years following graduation. Specific longer term outcomes to be monitored annually will include publications; presentations at national and international scientific meetings; grant proposals submitted and funded, with special attention to multidisciplinary grants and program project and center-type grants; mentorship and pertinent outcomes of mentoring others; research-related leadership posts and awards at local through international levels; and any evidence of commercial translation of research (e.g., business spin-offs, patents, etc.). Routine data will be collected using an internet-accessible survey, using a modified version of the Case School of Medicine Annual Faculty Activity Summary Form. The Case CCC Training Program Manager, Ms. Margy Weinberg, MSW, will assemble these and report them to the Steering Committee. In addition, each previous Scholar will be contacted by telephone to discuss and describe their career accomplishments and reflect on elements of the Certificate program that were particularly useful to them in their current positions.

6. TUITION

The Clinical Translational Oncology Research Scholar's Program (CTORSP) does not provide support for the Scholar's tuition.

Scholars are encouraged to apply for institutional training programs that provide tuition support.

Many employers provide a tuition benefit. Please contact your administrator or the Human Resources Department (Benefits Office) for limits/details.

Should the Scholar receive a fail or no pass, the Scholar will be required to repeat the course or take an alternative course within the two years of the Certificate program.

Clinical Translational Oncology Research Scholars Program (CTORSP) Leadership		
Directors	**Title**	**Affiliations**
Stanton L. Gerson, MD	Professor of Medicine (Hematology/Oncology); Director, CWRU and UHCMC, Director, Comprehensive Cancer Center; Director, Director, Ireland Cancer Center	CWRU and UHCMC
Alvin H. Schmaier, MD	Professor and Division Chief of Medicine	CWRU and UHCMC

	(Hematology/Oncology)	
Steering Committee	**Title**	**Affiliations**
Randall D. Cebul, MD	Professor of Medicine, Director of the Center for Health Care Research and Policy	CWRU and MetroHealth
Kevin Cooper, MD	Professor and Chair of Dermatology	CWRU and UHCMC
Clark W. Distelhorst, MD	Professor of Medicine (Hematology/Oncology) and Pharmacology	CWRU and UHCMC
Julian A. Kim, MD	Professor of Surgical Oncology	CWRU and UHCMC
John Letterio, MD	Professor and Division Chief of Pediatrics (Hematology/Oncology)	CWRU and UHCMC
Sanford D. Markowitz, MD, PhD	Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
Kurt C. Stange, MD, PhD	Professor of Family Medicine; Director, Center for Research in Family Practice & Primary Care	CWRU
Jackson T. Wright, Jr., MD, PhD, FCAP	Professor of Medicine	CWRU, UHCMC and VAMC
Mentors	**Title**	**Affiliations**
Nathan A. Berger, MD	Professor of Medicine (Hematology/Oncology), Experimental Medicine, Director, Center for Science, Health and Society	CWRU and UHCMC
Kevin D. Bunting, PhD	Associate Professor of Medicine (Hematology/Oncology),	CWRU and UHCMC
Kenneth R. Cooke, MD	Professor of Pediatrics,	Rainbow Babies and Children's Hospital and CWRU
Gregory S. Cooper, MD	Professor of Medicine (Gastroenterology)	CWRU and UHCMC
Kevin Cooper, MD	Professor and Chair of Dermatology	CWRU and UHCMC
Afshin Dowlati, MD	Associate Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
Robert C. Elston, PhD	Professor and Interim Chair of Epidemiology & Biostatistics	CWRU
Susan A. Flocke, PhD	Associate Professor of Family Medicine	CWRU and UHCMC
Sanjay Gupta, PhD	Associate Professor of Urology	CWRU
Charles L. Hoppel, MD	Professor of Clinical Pharmacology	CWRU and VAMC
David Kaplan, MD, PhD	Professor of Pathology	CWRU
Jeffery A. Kern, MD	Professor and Chief of Pulmonary and Critical Care Division	CWRU and UHCMC
Eric A. Klein, MD	Professor of Urology, CWRU; Chair of Urology, Cleveland Clinic	CWRU and Cleveland Clinic
Eric D. Kodish, MD	Professor and Chair of Bioethics, Cleveland Clinic; Professor of Pediatrics and Bioethics, CWRU	CWRU and Cleveland Clinic
Mary J. Laughlin, MD	Associate Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
Hillard M. Lazarus, MD	Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
John Letterio, MD	Professor and Division Chief, Pediatrics (Hematology/Oncology)	CWRU and UHCMC
Sanford D. Markowitz, MD, PhD	Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
Keith R. McCrae, MD	Professor of Medicine (Hematology/Oncology)	CWRU and UHCMC
Robert H. Miller, PhD	Professor of Neurosciences and Neurological	CWRU

	Surgery	
Nancy L. Oleinick, PhD	Professor of Radiation Oncology	CWRU and UHCMC
Paula Silverman, MD	Associate Professor of Medicine (Hematology/Oncology) ,	CWRU and UHCMC
Andrew E. Sloan, MD, FACS	Associate Professor of Neurological Surgery	CWRU and UHCMC
Kurt C. Stange, MD, PhD	Professor of Family Medicine; Director, Center for Research in Family Practice & Primary Care	CWRU
Steven E. Waggoner, MD	Associate Professor of Reproductive Biology, Division Chief of Gynecological Oncology	CWRU and UHCMC
Georgia L. Wiesner, MD	Associate Professor of Genetics	CWRU and UHCMC
Yu-Chung Yang, PhD	Professor of Biochemistry	CWRU

CASE WESTERN RESERVE UNIVERSITY
SCHOOL OF MEDICINE

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Dean
Vice President for Medical Affairs

School of Medicine

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June 18, 2009

Alan D. Levine, Ph.D.
Chair, Graduate Studies Committee
Case Western Reserve University
School of Medicine

To the Faculty Senate,

I endorse the development of the Clinical Oncology Research Training Program Certificate program led by Drs. Gerson and Schmaier that was recently reviewed by members of Faculty Senate. In the intervening period since review, it became clear to me that we do not have a satisfactory process at the School of Medicine, nor at the University, to review new or continuing certificate programs, and I apologize for any contributions from the SOM to the confusion. I have now reviewed the proposal, and support it. In particular, I would like to address several concerns that were apparently raised about the proposed certificate program.

1. Why is it a certificate, rather than a MS program? This certificate program has a clear focus on Cancer Biology training for junior clinical oncology faculty who are supported by an extramural training program for the express purpose of enhanced clinical oncology training. There is little career currency for these folks who already hold an MD in completing the components of an academic master's degree, but much to be gained in developing their specific knowledge and interests in cancer clinical trials. I should add that such certificates are becoming the rule in clinical research, to demonstrate a basic level of competency in these areas of study. In particular, the certificate will demonstrate that the scholars have fulfilled the basic course requirements of the program and developed their abilities to cogently write a translational clinical trial. The proposed certificate outlines 19 curricular hours in a thoughtful plan of study that allows other professional work to continue, while most MS programs require perhaps twice as many hours of coursework. Thus, it is a focused program with a focused purpose in training young faculty to prepare cancer therapeutics clinical trials.

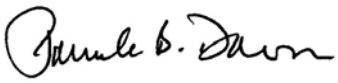
2. Does it duplicate the CRSP program? The Clinical Scholars Research Program, currently led by Dr. Randy Cebul, in the process of transition to the Center for Clinical Investigation as an academic home, is an approved MS degree intended for individuals who have completed their clinical training and wish to develop a professional career based upon clinical investigation, rather broadly. The CRSP is a Master's "Plan A"

substantial academic and research program that requires 36 credit hours including a formal thesis. Scholars may receive up to 18 hours of credit for thesis research. Scholars select one of four areas of concentration or specialty tracks with additional required coursework: Clinical Trials; Health Services/Outcomes Research; or Multidisciplinary/Translational Research. Some specific course electives are likely to be attractive to trainees in each program, but it is clear that the CRSP is a more substantive undertaking for which a MS is conferred, and had a broader scope. The CTSC (Clinical and Translational Science Collaborative) has considered adding a certificate program, and is actively working on a PhD curriculum, but at the present time only the MS is approved. Our faculty are active on national committees that are setting the standards for competencies at each of these levels, and the proposed certificate program is in line with national expectations.

3. Why wasn't there a letter from the Dean? Although both the SOM and Faculty Senate have clear review mechanisms for doctoral and master's programs (through Graduate Education and Faculty Affairs, and that require Dean's support), certificate programs currently fall between the cracks, both for initial review of new certificates and for periodic quality review once underway. It was not clear to any of us that a Dean's letter was required. To my knowledge, the SOM administers only one other certificate program (in Global Health). We will take steps to clarify that the initial review process for certificates is similar to that of a Master's program at the SOM. I anticipate that this will reduce confusion in the future.

I apologize for the delay in providing this information to you.

Sincerely,



Pamela B. Davis, M.D., Ph.D.

cc: Charles E. Rozek, Ph.D.
Dean, School of Graduate Studies
Case Western Reserve University

Certificate in Clinical Translational Oncology Research
Support Statement

The certificate program has its basis in the NCI funded K12 Clinical Oncology Research Program (CORP). The goal of the NCI in establishing this program is to train the next generation of oncology physician scientists who "1) primarily perform clinical oncology therapeutic research that develops and tests scientific hypotheses based on fundamental and clinical research findings, 2) design and test hypothesis-based, clinical therapeutic protocols and adjunct biological analyses and for clinician candidates to administer all phases (i.e., pilot/Phase I, Phase II, and Phase III) of cancer therapeutic clinical trials, and 3) conduct cancer therapeutic research in team research settings in which basic research and clinical scientists collaborate and interact to expedite the translation of basic science research discoveries into patient-oriented therapeutic cancer research." (NIH program announcement 06-449). Further, the certificate program provides an excellent roadmap for training a broader range of junior faculty and senior fellows in cancer therapeutic clinical research, and thus will be open to additional trainees beyond those enrolled in the NCI K12.

The certificate program codifies the expectations of the CORP curriculum, which requires K12 awardees to specify the didactic, clinical research and basic science research core components that trainees must complete to "graduate" from the program. Thus the certificate program that is proposed is targeted to oncology specialties and is heavily weighted toward specific elements that are deemed essential to a career in cancer research. Among these elements are:

Teaching the language and concepts of translational research and guiding them in the development of a hypothesis and specific aims of an original laboratory research question;

Instructing in critical aspects of managing a Phase I cancer clinical trial, with particular emphasis on incorporating laboratory research and correlative science and managing the regulatory, legal and ethical issues involved in the clinical trial for cancer patients; overseeing quality collection and management of data, monitoring for evidence of adverse or beneficial treatment effects, data analysis procedures;

Teaching analysis and evaluation of all aspects of Phase I trials including such topics as intent to treat analysis, analysis of compliance data, equivalency testing, multiple comparisons, and sequential testing.

Mentoring fellows in their professional development so that they may collaborate effectively with interdisciplinary colleagues.

These elements are part of the required curriculum which is supplemented by elective courses that are taken through CRSP. The focus and challenge of the clinical translational oncology research program is to provide a strong curriculum for training junior faculty in oncologic specialties and to do this in a way that incorporates as much practical application as possible, minimizing classroom hours and emphasizing individual mentorship to prepare them to develop strong and worthwhile hypotheses and develop proposals for research for improving the medical care of cancer patients that may be successfully supported by extramural funding agencies.

PI: Stanton L. Gerson, MD
Case Comprehensive Cancer Center

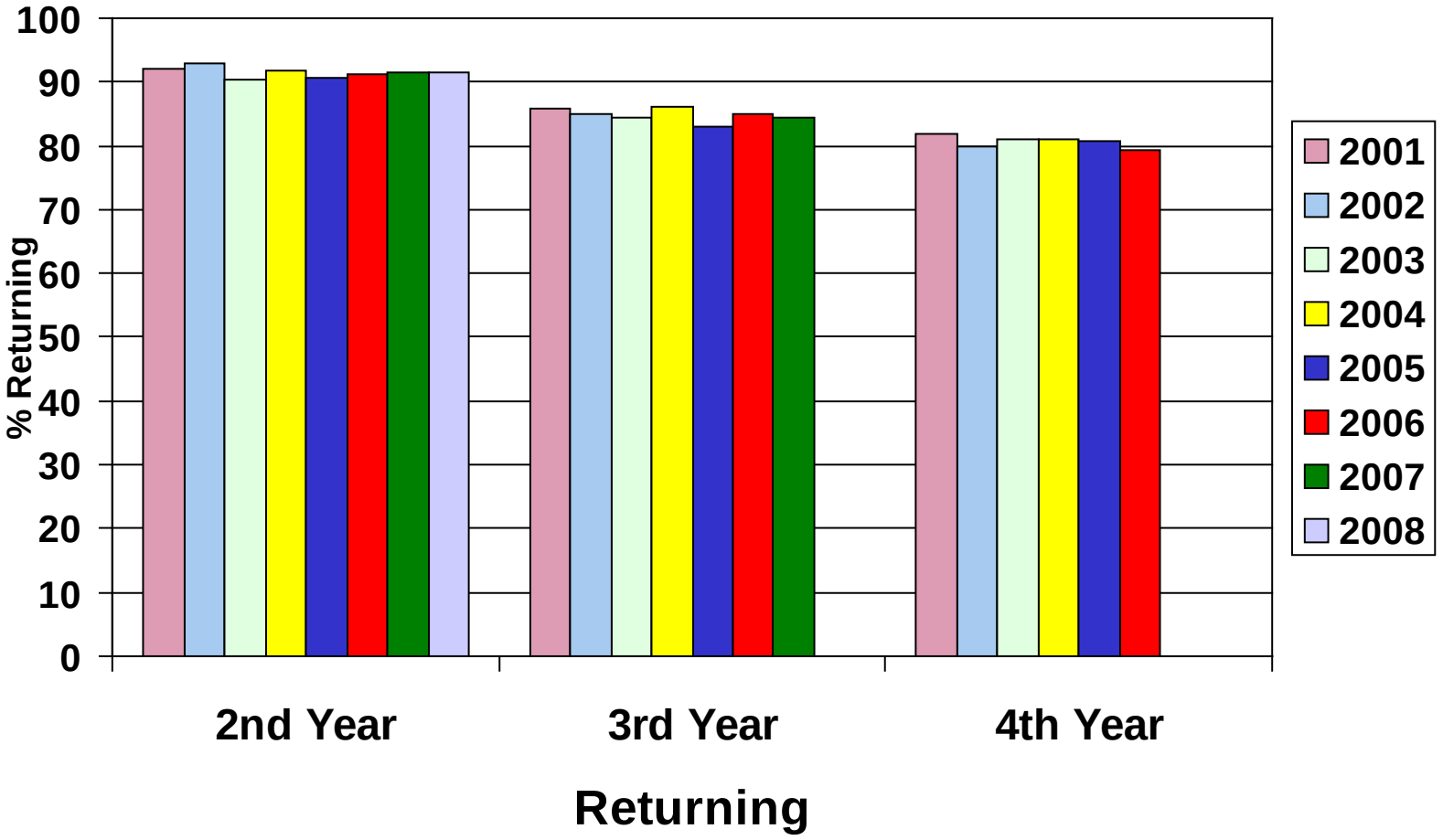
Margy Weinberg 216-844-5375
Administration

Office of Undergraduate Studies

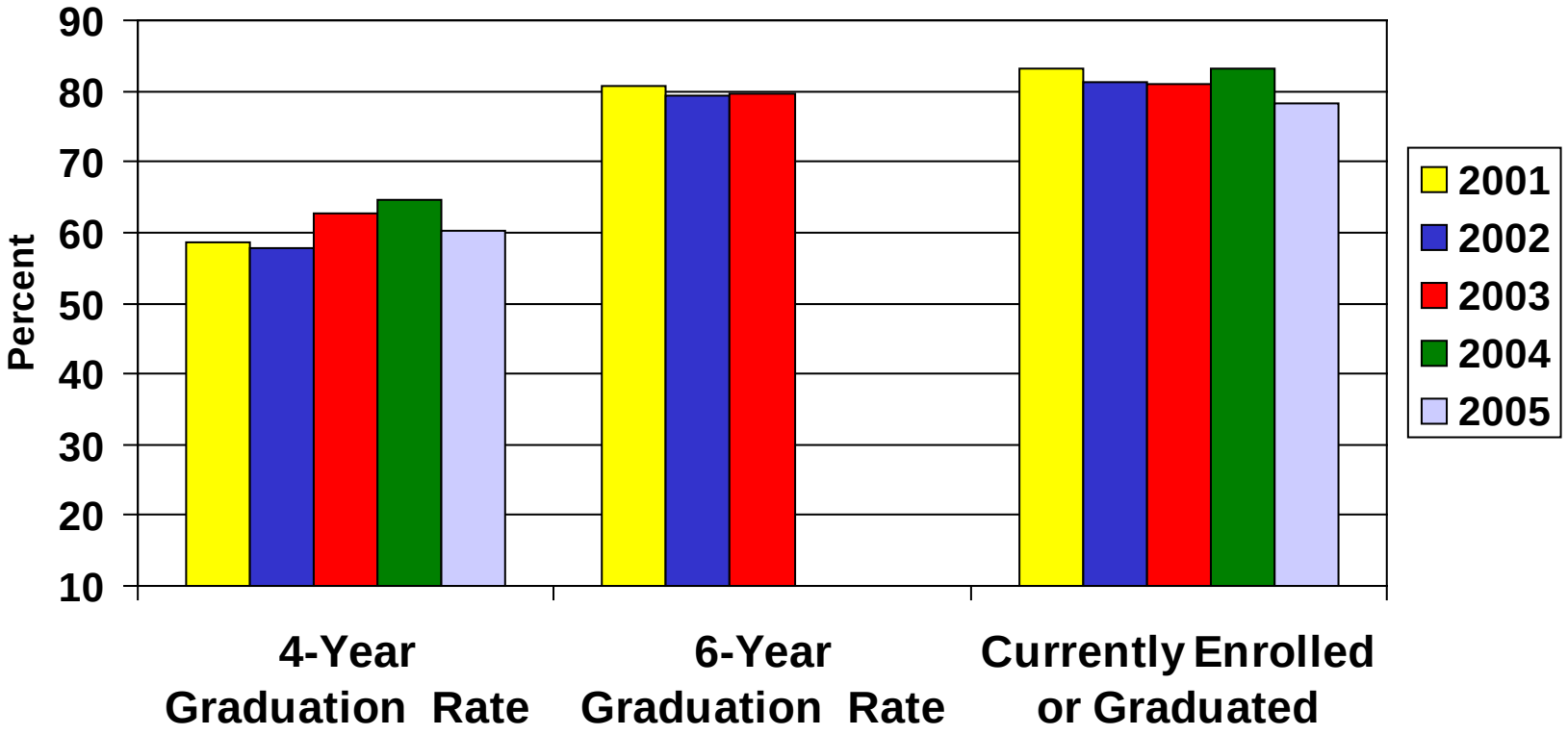
Fall 2009

Undergraduate Retention

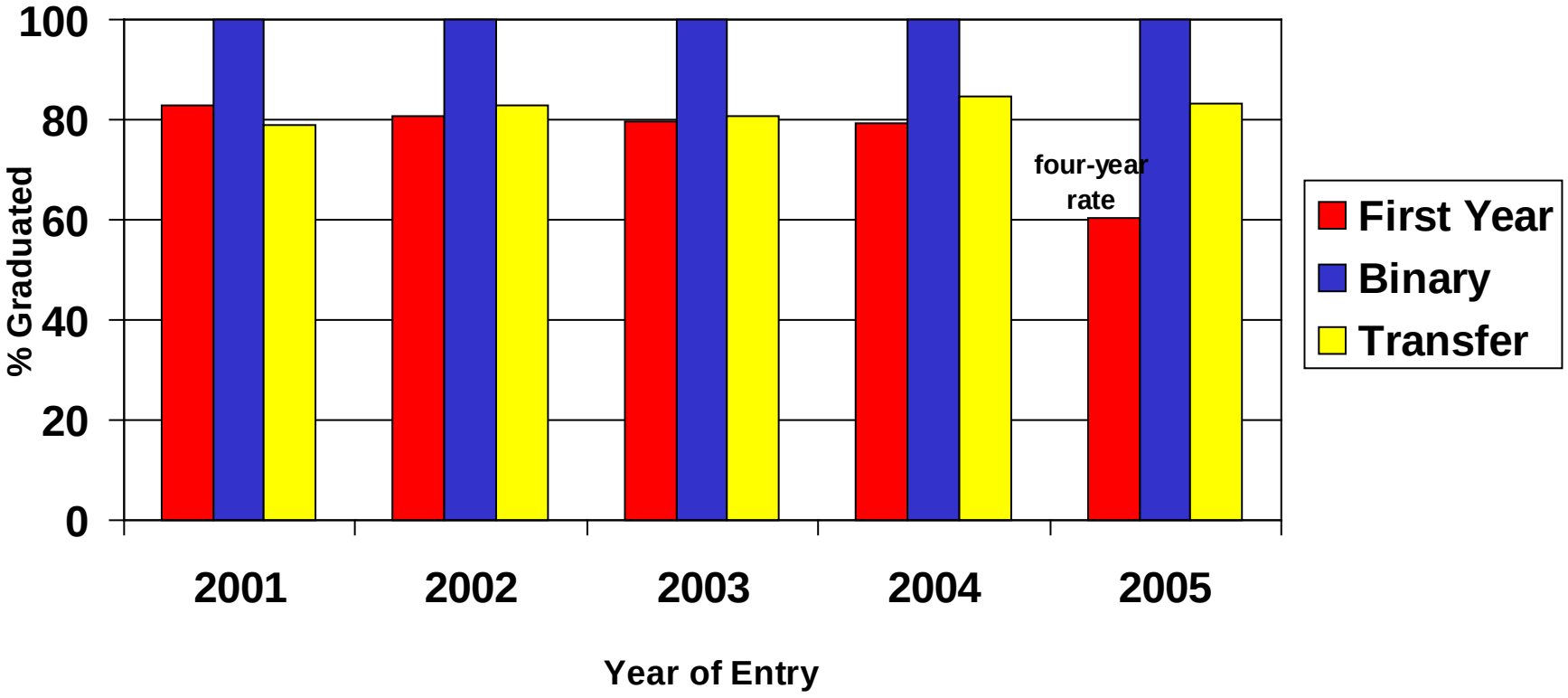
% Returning by Year of Entry



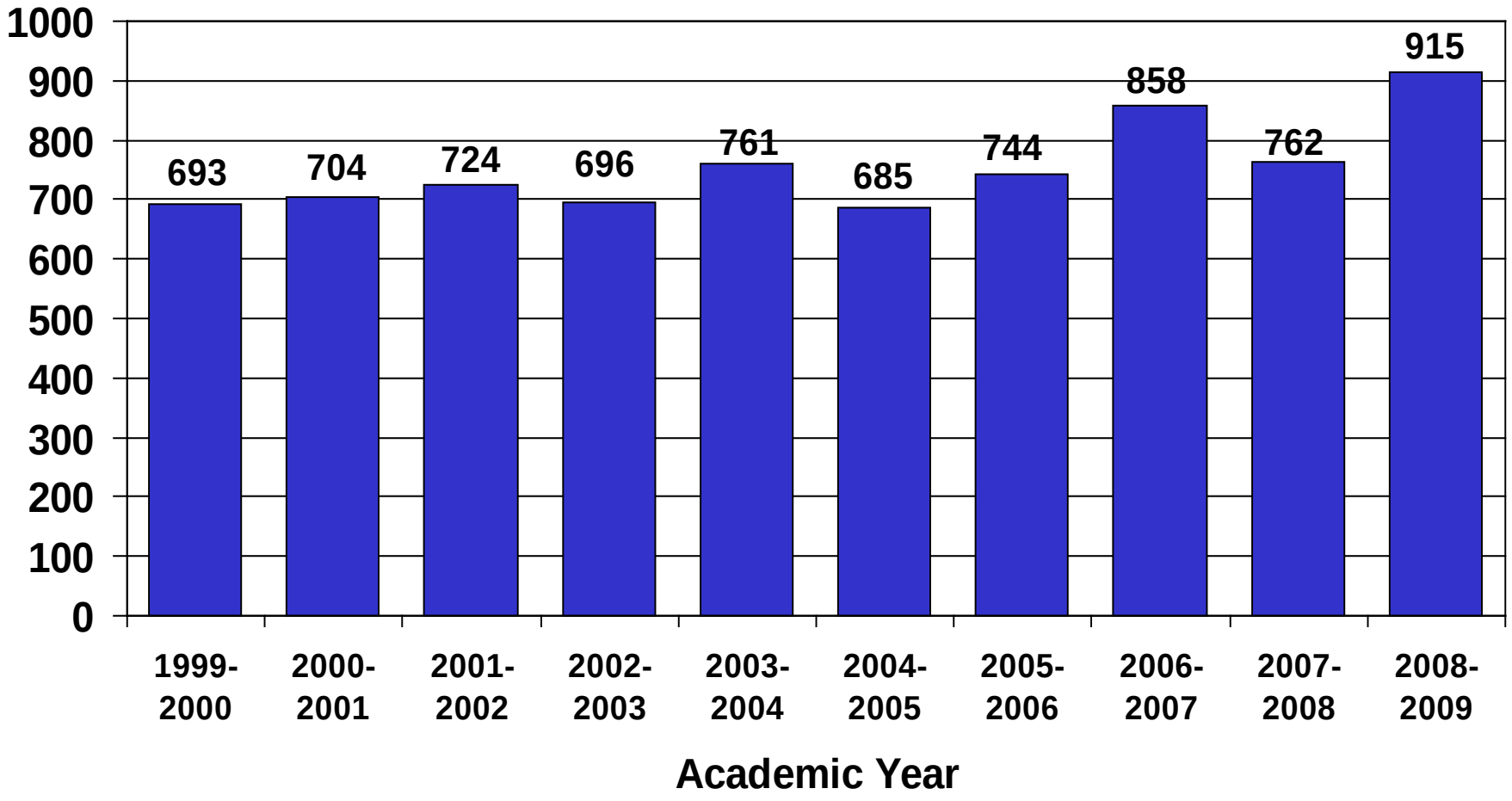
Undergraduate Graduation Rates (%)
by Year of Entry



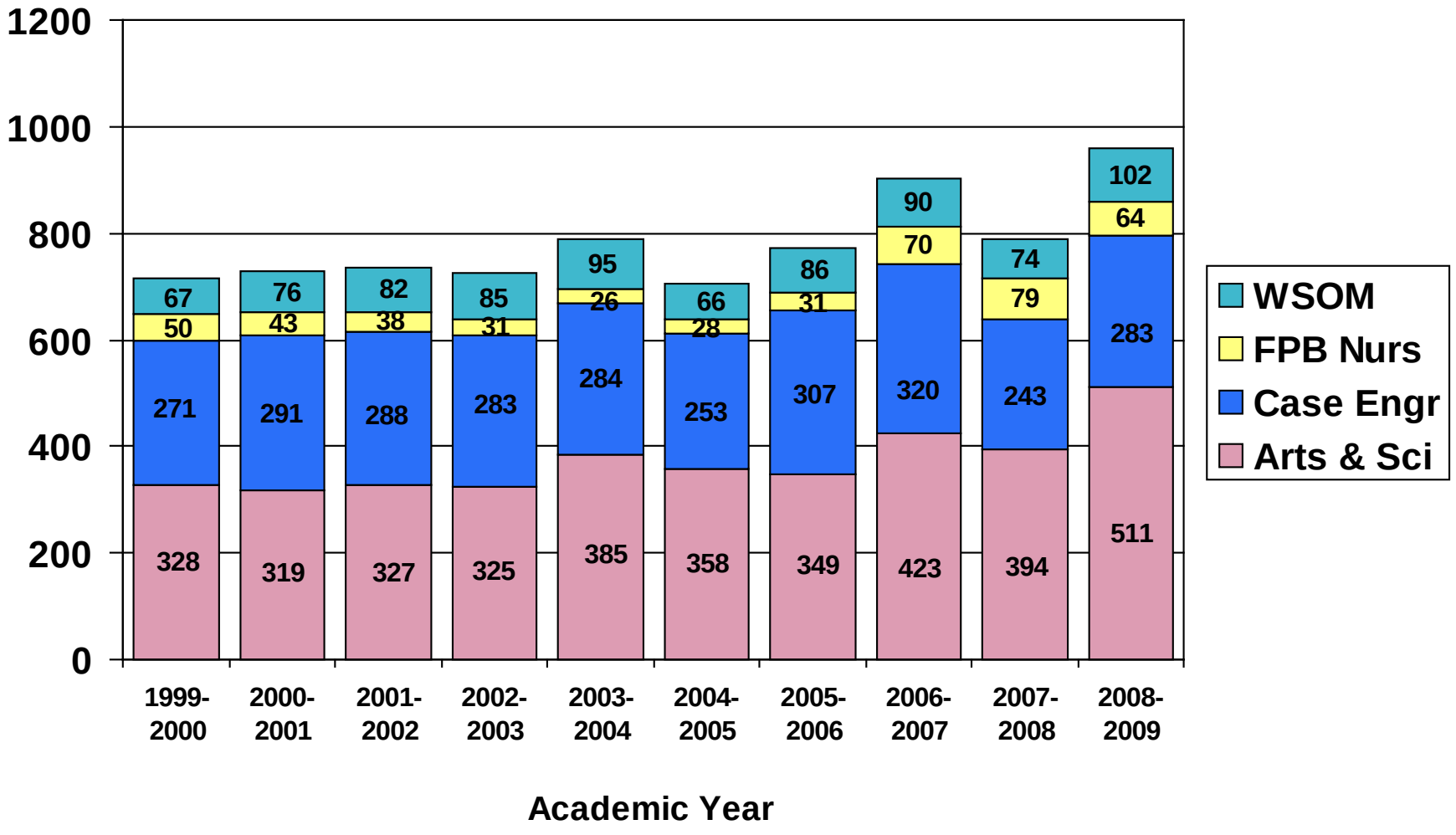
Percent Graduated by Year of Entry by Student Type

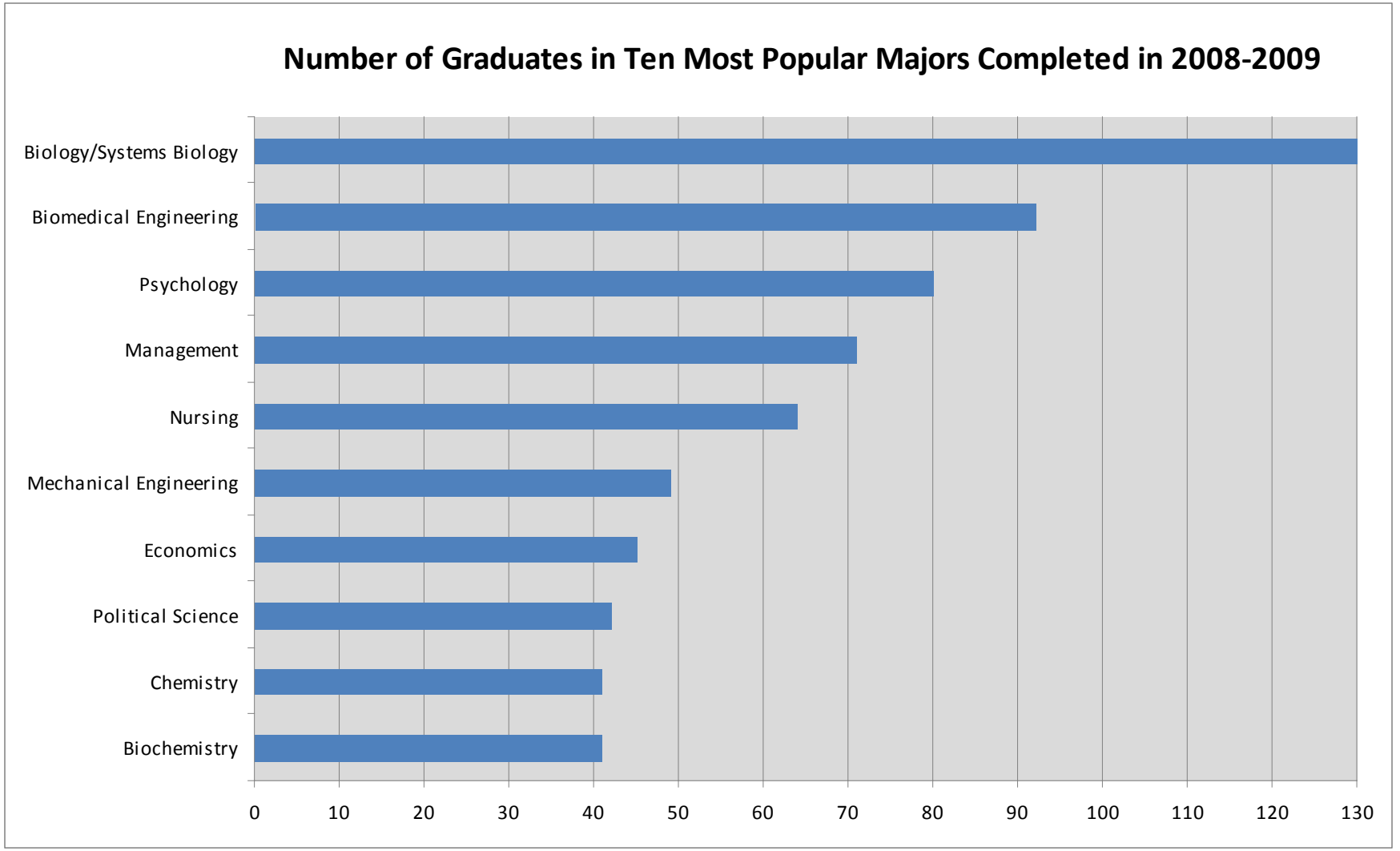


Total Number of Graduates

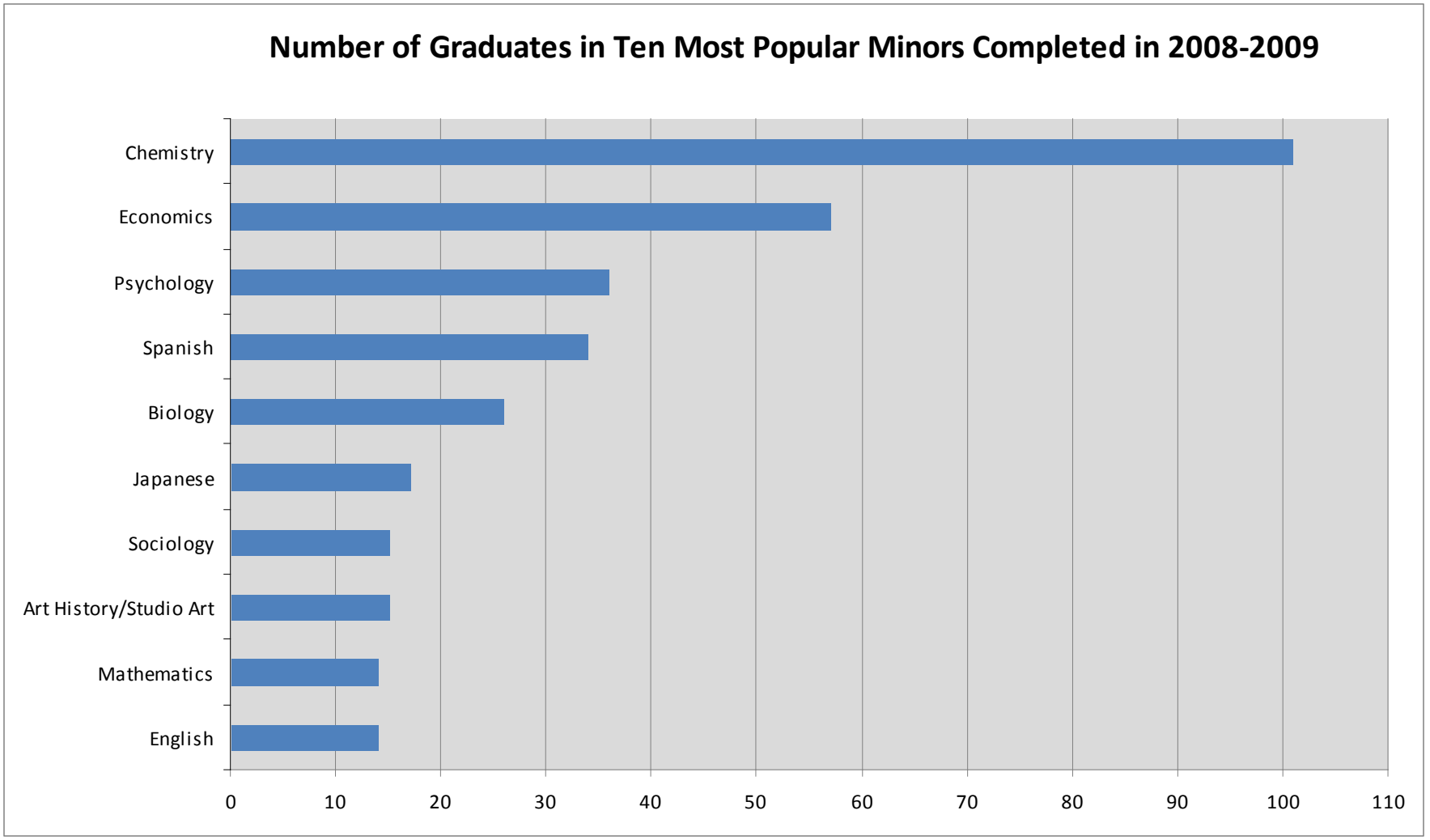


Total Number of Degrees



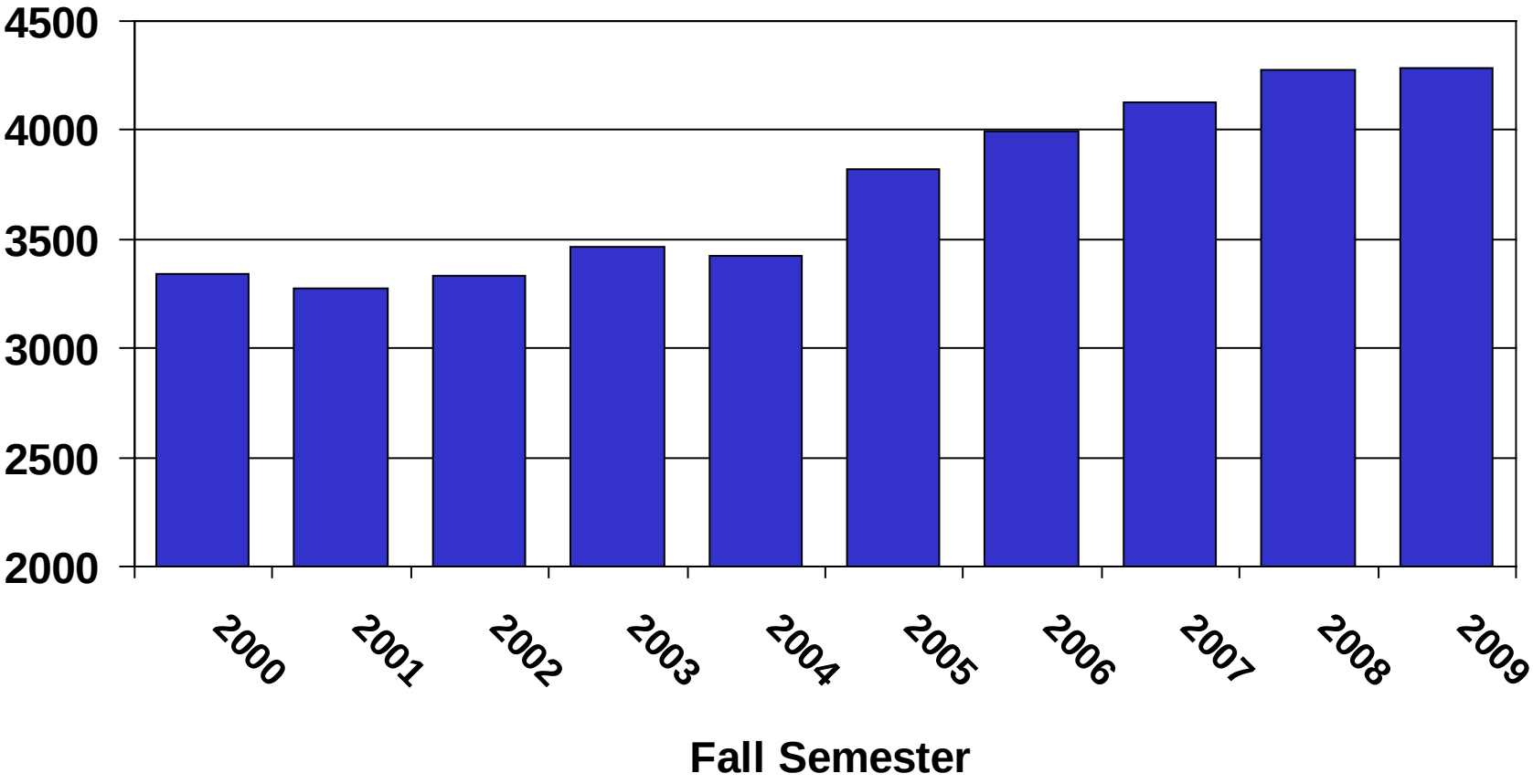


https://www.case.edu/provost/ugstudies/graduating/gradstats/gradstats.htm

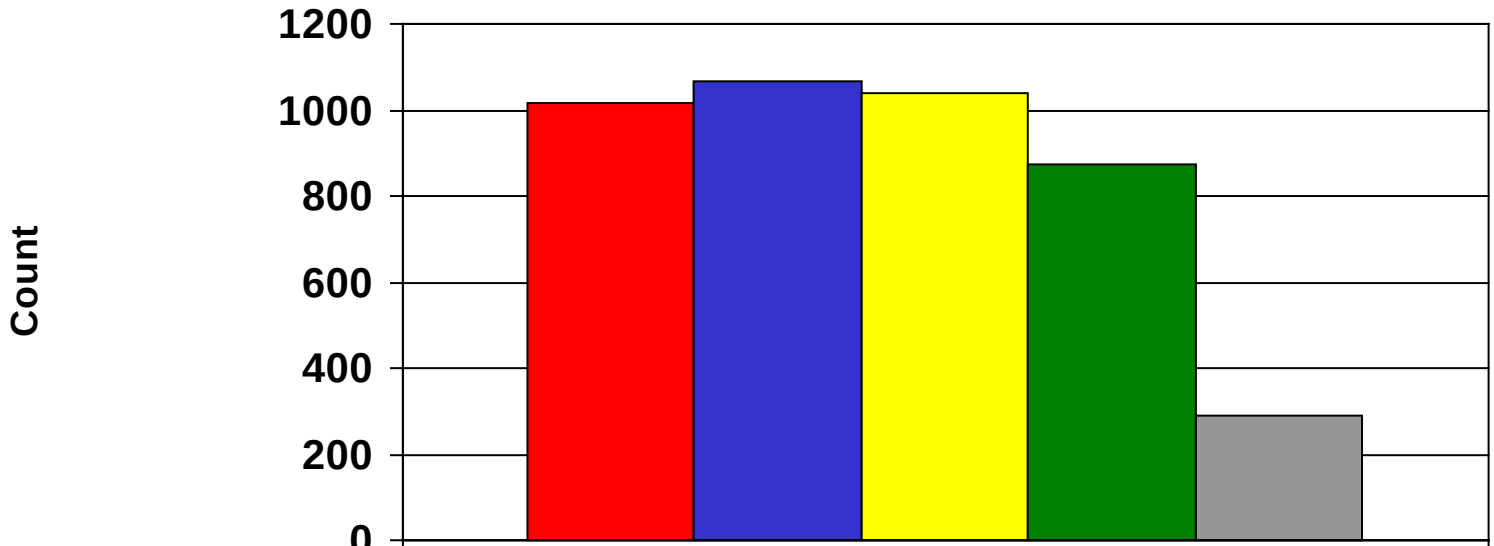


https://www.case.edu/provost/ugstudies/graduating/gradstats/gradstats.htm

Degree-Seeking Undergraduate Student Enrollment



Degree-Seeking Students by Admit Term*



2009-2010	1016
2008-2009	1068
2007-2008	1039
2006-2007	872
2005-2006 or earlier	291

STUDENT RETENTION BY GENDER

Entering Cohort	Number Starting	Percent Starting	Returned Second Year		Returned Third Year		Returned Fourth Year		Graduated in Four or Fewer Years		Graduated in Five or Fewer Years		Graduated in Six or Fewer Years		Total Graduated to Date		Currently Enrolled	Enrolled or Graduated	
2001-2002																			
Men	449	60.8%	415	92.4%	379	84.4%	365	81.3%	227	50.6%	341	75.9%	355	79.1%	363	80.8%	3	366	81.5%
Women	289	39.2%	264	91.3%	254	87.9%	240	83.0%	205	70.9%	239	82.7%	241	83.4%	247	85.5%	0	247	85.5%
ALL Students	738	100%	679	92.0%	633	85.8%	605	82.0%	432	58.5%	580	78.6%	596	80.8%	610	82.7%	3	613	83.1%
2002-2003																			
Men	514	61.5%	478	93.0%	437	85.0%	405	78.8%	264	51.4%	385	74.9%	397	77.2%	407	79.2%	3	410	79.8%
Women	322	38.5%	298	92.5%	273	84.8%	263	81.7%	218	67.7%	263	81.7%	267	82.9%	268	83.2%	1	269	83.5%
ALL Students	836	100%	776	92.8%	710	84.9%	668	79.9%	482	57.7%	648	77.5%	664	79.4%	675	80.7%	4	679	81.2%
2003-2004																			
Men	526	60.0%	467	88.8%	427	81.2%	413	78.5%	291	55.3%	384	73.0%	398	75.7%			10	408	77.6%
Women	351	40.0%	325	92.6%	313	89.2%	298	84.9%	260	74.1%	293	83.5%	301	85.8%			2	303	86.3%
ALL Students*	877	100%	792	90.3%	740	84.4%	711	81.1%	551	62.8%	677	77.2%	699	79.7%			12	711	81.1%
2004-2005																			
Men	478	60.9%	438	91.6%	406	84.9%	382	79.9%	282	59.0%	368	77.0%					22	390	81.6%
Women	307	39.1%	283	92.2%	270	87.9%	253	82.4%	225	73.3%	254	82.7%					9	263	85.7%
ALL Students	785	100%	721	91.8%	676	86.1%	635	80.9%	507	64.6%	622	79.2%					31	653	83.2%
2005-2006																			
Men	706	60.8%	629	89.1%	566	80.2%	563	79.7%	386	54.7%							148	534	75.6%
Women	456	39.2%	424	93.0%	398	87.3%	375	82.2%	314	68.9%							61	375	82.2%
ALL Students	1162	100%	1053	90.6%	964	83.0%	938	80.7%	700	60.2%							209	909	78.2%
2006-2007																			
Men	574	56.6%	519	90.4%	483	84.1%	448	78.0%	8	1.4%									
Women	441	43.4%	407	92.3%	379	85.9%	357	81.0%	5	1.1%									
ALL Students	1015	100.0%	926	91.2%	862	84.9%	805	79.3%	13	1.3%									
2007-2008																			
Men	641	56.6%	580	90.5%	524	81.7%													
Women	492	43.4%	457	92.9%	431	87.6%													
ALL Students	1133	100.0%	1037	91.5%	955	84.3%													
2008-2009																			
Men	584	56.9%	530	90.8%															
Women	442	43.1%	408	92.3%															
ALL Students	1026	100.0%	938	91.4%															
2009-2010																			
Men	564	58.4%																	
Women	402	41.6%																	
ALL Students	966	100.0%																	

*One student delayed matriculation from 2003 to 2004.

Office of Undergraduate Studies
Fall, 2009

STUDENT RETENTION BY ETHNICITY

Entering Cohort	Number Starting	Percent Starting	Returned Second Year		Returned Third Year		Returned Fourth Year		Graduated in Four or Fewer Years		Graduated in Five or Fewer Years		Graduated in Six or Fewer Years		Total Graduated to Date		Currently Enrolled	Enrolled or Graduated	
2001-2002																			
Non-resident aliens	25	3.4%	20	80.0%	16	64.0%	12	48.0%	9	36.0%	11	44.0%	12	48.0%	16	64.0%	0	16	64.0%
Black, non-Hispanic	33	4.5%	26	78.8%	24	72.7%	22	66.7%	14	42.4%	21	63.6%	22	66.7%	23	69.7%	0	23	69.7%
Asian or Pacific Islander	129	17.5%	122	94.6%	111	86.0%	105	81.4%	86	66.7%	106	82.2%	108	83.7%	109	84.5%	0	109	84.5%
Hispanic	14	1.9%	12	85.7%	9	64.3%	9	64.3%	6	42.9%	9	64.3%	9	64.3%	9	64.3%	0	9	64.3%
White, non-Hispanic	531	72.0%	494	93.0%	469	88.3%	452	85.1%	316	59.5%	432	81.4%	443	83.4%	450	84.7%	3	453	85.3%
Other or unknown	6	0.8%	5	83.3%	4	66.7%	5	83.3%	1	16.7%	1	16.7%	2	33.3%	3	50.0%	0	3	50.0%
TOTAL Students	738	100.0%	679	92.0%	633	85.8%	605	82.0%	432	58.5%	580	78.6%	596	80.8%	610	82.7%	3	613	83.1%
2002-2003																			
Non-resident aliens	23	2.8%	21	91.3%	14	60.9%	13	56.5%	9	39.1%	13	56.5%	14	60.9%	17	73.9%	1	18	78.3%
Black, non-Hispanic	39	4.7%	39	100.0%	30	76.9%	30	76.9%	17	43.6%	24	61.5%	26	66.7%	27	69.2%	0	27	69.2%
Asian or Pacific Islander	131	15.7%	124	94.7%	117	89.3%	110	84.0%	93	71.0%	110	84.0%	111	84.7%	112	85.5%	1	113	86.3%
Hispanic	20	2.4%	18	90.0%	12	60.0%	11	55.0%	8	40.0%	11	55.0%	11	55.0%	11	55.0%	0	11	55.0%
White, non-Hispanic	613	73.3%	564	92.0%	528	86.1%	496	80.9%	349	56.9%	483	78.8%	495	80.8%	501	81.7%	2	503	82.1%
Other or unknown	10	1.2%	10	100.0%	9	90.0%	8	80.0%	6	60.0%	7	70.0%	7	70.0%	7	70.0%	0	7	70.0%
TOTAL Students	836	100.0%	776	92.8%	710	84.9%	668	79.9%	482	57.7%	648	77.5%	664	79.4%	675	80.7%	4	679	81.2%
2003-2004																			
Non-resident aliens	22	2.5%	18	81.8%	13	59.1%	14	63.6%	7	31.8%	9	40.9%	11	50.0%			7	18	81.8%
Black, non-Hispanic	36	4.1%	36	100.0%	31	86.1%	28	77.8%	20	55.6%	25	69.4%	27	75.0%			1	28	77.8%
Asian or Pacific Islander	144	16.4%	132	91.7%	122	84.7%	118	81.9%	92	63.9%	112	77.8%	117	81.3%			0	117	81.3%
Hispanic	18	2.1%	15	83.3%	14	77.8%	14	77.8%	8	44.4%	14	77.8%	14	77.8%			0	14	77.8%
White, non-Hispanic	627	71.5%	562	89.6%	532	84.8%	511	81.5%	404	64.4%	491	78.3%	503	80.2%			4	507	80.9%
Other or unknown	30	3.4%	29	96.7%	28	93.3%	26	86.7%	20	66.7%	26	86.7%	27	90.0%			0	27	90.0%
TOTAL Students*	877	100.0%	792	90.3%	740	84.4%	711	81.1%	551	62.8%	677	77.2%	699	79.7%			12	711	81.1%
2004-2005																			
Non-resident aliens	25	3.2%	22	88.0%	19	76.0%	18	72.0%	8	32.0%	15	60.0%					6	21	84.0%
Black, non-Hispanic	46	5.9%	38	82.6%	37	80.4%	32	69.6%	20	43.5%	28	60.9%					5	33	71.7%
Asian or Pacific Islander	113	14.4%	104	92.0%	101	89.4%	90	79.6%	80	70.8%	90	79.6%					4	94	83.2%
Hispanic	19	2.4%	16	84.2%	12	63.2%	12	63.2%	7	36.8%	11	57.9%					0	11	57.9%
White, non-Hispanic	513	65.4%	477	93.0%	446	86.9%	427	83.2%	347	67.6%	424	82.7%					14	438	85.4%
Other or unknown	69	8.8%	64	92.8%	61	88.4%	56	81.2%	45	65.2%	54	78.3%					2	56	81.2%
TOTAL Students	785	100.0%	721	91.8%	676	86.1%	635	80.9%	507	64.6%	622	79.2%					31	653	83.2%
2005-2006																			
Non-resident aliens	20	1.7%	19	95.0%	16	80.0%	17	85.0%	12	60.0%							6	18	90.0%
Black, non-Hispanic	48	4.1%	40	83.3%	35	72.9%	34	70.8%	23	47.9%							10	33	68.8%
Asian or Pacific Islander	214	18.4%	202	94.4%	187	87.4%	179	83.6%	146	68.2%							32	178	83.2%
Hispanic	32	2.8%	27	84.4%	21	65.6%	19	59.4%	15	46.9%							6	21	65.6%
White, non-Hispanic	682	58.7%	616	90.3%	571	83.7%	562	82.4%	406	59.5%							126	532	78.0%
Other or unknown	166	14.3%	149	89.8%	134	80.7%	127	76.5%	98	59.0%							29	127	76.5%
TOTAL Students	1162	100.0%	1053	90.6%	964	83.0%	938	80.7%	700	60.2%							209	909	78.2%
2006-2007																			
Non-resident aliens	26	2.6%	23	88.5%	21	80.8%	18	69.2%	2	7.7%									
Black, non-Hispanic	66	6.5%	58	87.9%	56	84.8%	52	78.8%	0	0.0%									
Asian or Pacific Islander	201	19.8%	193	96.0%	175	87.1%	162	80.6%	5	2.5%									
Hispanic	20	2.0%	18	90.0%	16	80.0%	16	80.0%	0	0.0%									
White, non-Hispanic	632	62.3%	571	90.3%	538	85.1%	504	79.7%	6	0.9%									
Other or unknown	70	6.9%	63	90.0%	56	80.0%	53	75.7%	0	0.0%									
TOTAL Students	1015	100.0%	926	91.2%	862	84.9%	805	79.3%	13	1.3%									
2007-2008																			
Non-resident aliens	32	2.8%	26	81.3%	23	71.9%													
Black, non-Hispanic	62	5.5%	56	90.3%	48	77.4%													
Asian or Pacific Islander	145	12.8%	139	95.9%	133	91.7%													
Hispanic	29	2.6%	25	86.2%	20	69.0%													
White, non-Hispanic	618	54.5%	565	91.4%	526	85.1%													
Other or unknown	247	21.8%	226	91.5%	205	83.0%													
TOTAL Students	1133	100.0%	1037	91.5%	955	84.3%													
2008-2009																			
Non-resident aliens	26	2.5%	23	88.5%															
Black, non-Hispanic	65	6.3%	57	87.7%															
Asian or Pacific Islander	181	17.6%	169	93.4%															
Hispanic	26	2.5%	25	96.2%															
White, non-Hispanic	541	52.7%	494	91.3%															
Other or unknown	187	18.2%	170	90.9%															
TOTAL Students	1026	100.0%	938	91.4%															
2009-2010																			
Non-resident aliens	84	8.7%																	
Black, non-Hispanic	23	2.4%																	
Asian or Pacific Islander	168	17.4%																	
Hispanic	37	3.8%																	
White, non-Hispanic	519	53.7%																	
Other or unknown	135	14.0%																	
TOTAL Students	966	100.0%																	

"Other" category includes American Indian or Alaskan Native and unspecified ethnicities.

*One student delayed matriculation from 2003 to 2004.

Office of Undergraduate Studies
Fall, 2009

TRANSFER AND BINARY STUDENT RETENTION

Entering Cohort	Number Starting	Percent Starting	Returned Second Year		Currently Enrolled		Total Graduated to Date		Enrolled or Graduated	
2001-2002										
Binary	4	5.6%	4	100.0%	0	0.0%	4	100.0%	4	100.0%
Transfer	67	94.4%	59	88.1%	0	0.0%	53	79.1%	53	79.1%
ALL Students	71	100%	63	88.7%	0	0.0%	57	80.3%	57	80.3%
2002-2003										
Binary	7	8.4%	7	100.0%	0	0.0%	7	100.0%	7	100.0%
Transfer	76	91.6%	66	86.8%	0	0.0%	63	82.9%	63	82.9%
ALL Students	83	100%	73	88.0%	0	0.0%	70	84.3%	70	84.3%
2003-2004										
Binary	6	7.1%	6	100.0%	0	0.0%	6	100.0%	6	100.0%
Transfer	78	92.9%	67	85.9%	1	1.3%	63	80.8%	64	82.1%
ALL Students	84	100%	73	86.9%	1	1.2%	69	82.1%	70	83.3%
2004-2005										
Binary	3	3.4%	3	100.0%	0	0.0%	3	100.0%	3	100.0%
Transfer	85	96.6%	74	87.1%	0	0.0%	72	84.7%	72	84.7%
ALL Students	88	100%	77	87.5%	0	0.0%	75	85.2%	75	85.2%
2005-2006										
Binary	3	4.0%	3	100.0%	0	0.0%	3	100.0%	3	100.0%
Transfer	72	96.0%	68	94.4%	5	6.9%	60	83.3%	65	90.3%
ALL Students	75	100%	71	94.7%	5	6.7%	63	84.0%	68	90.7%
2006-2007										
Binary	3	4.3%	3	100.0%	0	0.0%	3	100.0%	3	100.0%
Transfer	67	95.7%	57	85.1%	25	37.3%	36	53.7%	61	91.0%
ALL Students	70	100%	60	85.7%	25	35.7%	39	55.7%	64	91.4%
2007-2008										
Binary	4	7.0%	4	100.0%	0	0.0%	4	100.0%	4	100.0%
Transfer	53	93.0%	49	92.5%	42	79.2%	3	5.7%	45	84.9%
ALL Students	57	100%	53	93.0%	42	73.7%	7	12.3%	49	86.0%
2008-2009										
Binary	3	4.5%	3	100.0%						
Transfer	63	95.5%	57	90.5%						
ALL Students	66	100%	60	90.9%						
2009-2010										
Binary	2	4.3%								
Transfer	44	95.7%						*Office of Undergraduate Studies*		
ALL Students	46	100%						*Fall, 2009*		

09-10 Budget Priorities

Proposal	cost	high (3)	medium (2)	low (1)	not (0)	Total Points
Undergraduate advising: a pool of funds to seed good undergraduate advising practices.	$50,000/year for 2 years, 5-10 project grants	20	16	6	4	98
Improve the websites for the Faculty Senate/Faculty Handbook/Faculty Senate By-laws.	$5,000	17	12	13	4	88
That $5-10k be used to investigate whether "Elder Care" could be added as a benefits option that faculty/staff could obtain.	$5,000	16	10	14	6	82
Espresso Book Machine®, a print-on-demand device that produces library quality paperbacks at low cost	$100,000	14	14	11	7	81
Outcome assessment: a two-year outcome assessment stimulus project is proposed.	$100,00	12	16	12	6	80
A study of increases in international undergraduate students to determine the most effective means for successfully affecting such increases.	$50,000	12	13	17	4	79

PROPOSAL TO CREATE A FSCUE STUDENT LIFE SUBCOMMITTEE

WHEREAS, according to the Faculty Handbook/Constitution as amended in the summer of 2009, the Faculty Senate Committee on Undergraduate Education (FSCUE) "shall be empowered to form subcommittees as it judges appropriate to discharge its duties and to appoint to these subcommittee voting members of the University Faculty, staff members from administrative units that serve the undergraduate mission, and undergraduate students;" and

WHEREAS, the Faculty Senate Bylaws state that "the establishment of any standing subcommittee shall be subject to approval by the Faculty Senate;" and

WHEREAS, the FSCUE has considered and endorsed the creation of a Student Life Subcommittee with the membership and authority described below;

NOW THEREFORE, IT IS HEREBY RESOLVED

THAT the Faculty Senate approves the formation of a FSCUE Student Life Subcommittee;

THAT the membership of the FSCUE Student Life Subcommittee be the following voting and non-voting members:

Voting Members
Vice President for Student Affairs (*ex officio*), Chair
Dean of Undergraduate Studies (*ex officio*)
Four regular members of the Undergradaute Program Faculty divided equitably among the constituent faculties, chosen by the FSCUE in consultation with the Vice President for Student Affairs for terms of three years
Three student members chosen by the Undergraduate Student Government for terms of one year

Non-voting Members
Associate Vice President for Student Affairs for Campus Life
Director of Athletics and Chairman of Physical Education

THAT the Subcommittee will have the responsibility to provide faculty oversight and advice on the full range of programs, facilities, and services for students beyond the classroom to assure a student experience that is rich, varied, and consistent with academic programs.

THAT the Subcommittee will have the following responsibilities:

a. Establish and monitor policies and processes related to academic integrity.
b. Advise on programs and resources that support curricular programs, including but not limited to tutoring, disability accommodations, career services, athletics, etc.
c. Advocate for facilities, programs, and services faculty believe will improve the student experience and further university priorities, e.g. internationalization.
d. Seek and consider student opinions and recommendations from members of the committee, Undergraduate Student Government, and survey information.
e. Review and make recommendations to FSCUE on specific policies, departments, and programs as appropriate.
f. Act in an advisory capacity to the Vice President for Student Affairs.

GEN, 11/6/2009

PROPOSAL TO CREATE A FSCUE ACADEMIC STANDING SUBCOMMITTEE

WHEREAS, according to the Faculty Handbook/Constitution as amended in the summer of 2009, the Faculty Senate Committee on Undergraduate Education (FSCUE) "shall be empowered to form subcommittees as it judges appropriate to discharge its duties and to appoint to these subcommittee voting members of the University Faculty, staff members from administrative units that serve the undergraduate mission, and undergraduate students;" and

WHEREAS, the Faculty Senate Bylaws state that "the establishment of any standing subcommittee shall be subject to approval by the Faculty Senate;" and

WHEREAS, the FSCUE has considered and endorsed the creation of an Academic Standing Subcommittee with the membership and authority described below;

NOW THEREFORE, IT IS HEREBY RESOLVED

THAT the Faculty Senate approves the formation of a FSCUE Academic Standing Subcommittee.

THAT the membership of the FSCUE Academic Standing Subcommittee be the following voting and non-voting members:

Voting Members
Dean of Undergraduate Studies (*ex officio*), Chair
Vice Provost for Undergraduate Education (*ex officio*)
Six regular members of the Undergradaute Program Faculty divided equitably among the constituent faculties, chosen by the FSCUE in consultation with the Dean of Undergraduate Studies for terms of three years
One student member chosen by the Undergraduate Student Government for a term of one year

Non-voting Members
Staff members in Undergraduate Studies who have direct responsibility for advising students on registration and academic standing matters, as designated by the Dean of Undergraduate Studies
A designee of the Vice President for Student Affairs
Two designees of the Vice President for Enrollment Management, ordinarily the Director of Undergraduate Admissions and the Director of Financial Aid

THAT the Subcommittee will have the responsibility to review and recommend to the FSCUE as to standards for undergraduate academic standing and honors, standards for the retention of merit-based scholarships and the awarding of new merit-based scholarships to already-matriculated students, the structure and composition of the grading system, and other academic policies and procedures that extend across all undergraduate degree programs.

THAT the Subcommittee absent the student member shall be referred to as the Undergraduate Academic Standing Board and will have the following responsibilities:

a. To exercise the authority given to the FSCUE in the Faculty Handbook to interpret existing policies and apply existing academic rules to decide cases that involve academic probation, separation, and readmission; to decide cases of the retention of merit-based scholarships and the

awarding of new merit-based scholarships to already-matriculated students; and to report its actions to the FSCUE as well as to the appropriate administrative offices;

b. To review student petitions for exceptions to administrative and academic rules that extend across all undergraduate degree programs.

THAT the Undergraduate Academic Standing Board may delegate the routine application of academic probation criteria, readmission criteria, merit-scholarship retention rules, honors criteria, and administrative and academic rules that extend across all undergraduate degree programs to the Dean of Undergraduate Studies, while retaining authority in these matters.

JW, 10/22/2009